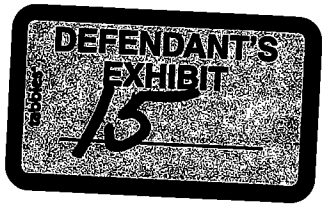
EXHIBIT 15

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

BOBBY R. MILLIGAN, et al., Plaintiffs, -vs- ACTAVIS GROUP HF, et al., Defendants.	MDL Case No. 2:09-cv-121 VIDEOTAPED DEPOSITION OF: RUSSELL F. SOMMA, PH.D.

TRANSCRIPT of testimony as taken by and before MARK SCHAFFER, a Certified Shorthand Reporter and Notary Public of the States of New Jersey and New York, at the Marriott Hotel, Newark Liberty International Airport, Newark, New Jersey, on Thursday, July 1, 2010, commencing at 8:31 in the forenoon.



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ALSO PRESENT: ADAM DICOLA, Videographer

I N D E X

E X H I B I T S

THE VIDEOGRAPHER: Good morning. We are now on the record at 8:31 a.m. The date today is July 1st, 2010. This is the videotaped deposition of Dr. Russell F. Somma in the matter of In Re: Digitek Product Liability Litigation in the United States District Court for the Southern District of West Virginia, Charleston Division, MDL Case Number 2:02-CV-121.

I am the videographer; my name is Adam Dicola of Rennillo Court Reporting. The court reporter is Mark Schaffer, also with Rennillo Court Reporting.

Will counsel please state their appearances for the record?

MR. MILLER: Pete Miller with the Miller firm for plaintiffs.

MS. CARTER: Meghan Carter with Motley, Rice for the plaintiffs.

MS. DOWNIE: Ericka Downie, Shook, Hardy & Bacon, for the Mylan defendants.

MR. MORIARTY: Mathew Moriarty, Tucker Ellis & West, for the Actavis defendants.

R U S S E L L F. S O M M A,

Five Shady Lane, Sparta, New Jersey 07871,

having been duly sworn according to law by the Officer, testified as follows:

DIRECT EXAMINATION BY MR. MORIARTY:

MR. MILLER: Matt, before you get started, I would like to point out something. I spoke to the doctor yesterday evening and he saw what he believes to be something in error in his report that he'd like to fix. We can address it now or wait until you discuss the report.

MR. MORIARTY: Let's wait.

MR. MILLER: Okay.

Q. Let me know.

A. Okay.

Q. Good morning.

A. Thanks. Thanks. Good morning to you.

Q. How many times have you had your deposition taken before?

A. Never.

Q. Other than the Digitek litigation, how many times have you been consulted as an expert witness?

A. Never.

Q. I'm sure Mr. Miller or Ms. Carter has given you some information about what's going to happen today. Okay? Is that right?

A. Yes, sir.
Q. We are going to spend all day. I'm going to ask you a lot of questions. And your function is to just to answer my questions; okay?
A. Yes, sir.
Q. If you do not understand my question, please tell me you don't understand my question. Okay?
A. Okay.
Q. If you answer the question, I'm going to understand -- I'm going to assume that you at least understood it. Is that okay?
A. Okay. I will ask.
Q. Okay.
A. No stretching.
Q. And if you need to look at documents, please look at documents. I don't want you to guess at the answers to any of my questions. Okay?
A. Okay.
Q. And also sometimes witnesses want to talk and talk and talk and lecture me about good manufacturing practices and various other topics. I'm going to try to keep my questions quite specific. Okay?
A. Okay.
Q. So if you can answer my questions, I would appreciate that. Okay?

A. Okay. So that would mean that there would have to be some exchange between us, so I understand exactly --

Q. Yes. I'll give you a chance to explain if I need something explained, but I would like direct answers to my questions. Okay?

A. Uh-huh, yes, sir.

Q. This is Exhibit 51.

Is that your resume?

A. Yes, it is.

Q. All right. And while I'm at it, this is Exhibit 52.

A. That's my report, yes.

Q. Is this your report --

A. Yes.

Q. -- in this litigation?

A. Uh-huh, yes, it is.

Q. And at the back of your report in Appendix A, it says, "Materials reviewed." Right?

A. Yes, sir.

Q. And I assume that at least before writing the report, these are the things that you looked at. Is that correct?

A. That's correct.

Q. And when were you first consulted in this

litigation?

A. I was contacted in March.

Q. Of 2010?

A. Of 2010.

Q. So I assume as you received material over time, you have had an opportunity to read it?

A. As I got the material I did read it, yes.

Q. And you had plenty of time to draft this report. Is that correct?

A. Yes, sir.

Q. I assume that there were drafts to this report?

A. Yes, sir.

Q. Did you save drafts?

A. Yes, I did.

Q. And then I assume that you had some time to talk with members of the plaintiffs' side of this case about those drafts leading to the final version. Is that right?

A. That's correct, yes.

Q. Okay. And that's fine. You have never done this before. You didn't know anything about it. They gave you some guidance on things that may need to be in there or not; right?

A. Well, Matt, actually what I did --

MR. MILLER: Object to form.
Q. One rule is you have to let me finish my questions --
A. Sorry, sorry.
Q. Because, Mark, the court reporter, can't take us both down at the same time.
A. I got you.
Q. Okay?
A. I got you.
Q. Okay.
A. Can I ask my question now?
Q. Well, actually you don't get to ask questions.
A. Oh, okay.
Q. I do.
MR. MILLER: But there is a question pending. You had asked him --
MR. MORIARTY: I asked if he had time to talk with the plaintiffs' side about the report.
A. Right, and I agreed.
Q. Okay. And there -- there is a mistake in it somewhere and we'll get to that later.
A. Right.
Q. Okay?
A. Uh-huh.

Q. Did the plaintiffs' side of the case let you know, the lawyers let you know, that the purpose of this report is to put people like me on notice of what your opinions were in the litigation?

A. Yes, sir.

Q. And you tried to put all your opinions in there?

A. That I came away with after I read what I had, my opinions based on my experience, yes.

Q. Have you read additional material since writing this report?

A. Yes, sir, I have.

Q. We'll get to that later.

Okay. So you were first contacted in March. And who contacted you?

A. An organization by the name of Spyglass. They were looking for somebody to provide expert input, with experience in tableting.

Q. I assume you mean --

(A discussion is held off the record.)

A. With experience in tableting. Compression. Sorry.

Q. I assume you mean Mark Kenny?

A. That's correct, right.

Q. And did he make direct contact with you?

A. Yes, he did.
Q. Have you ever met him before?
A. Not before then, no.
Q. How did he know about you?
A. A network of consultants; knows people, and they worked with another fellow that I worked with at Novartis.
Q. What's his name?
A. Alp Yaman.
Q. I'm sorry?
A. Alp Yaman.
Q. Now, you have a company called Somma Tech Consulting; do you not?
A. That's correct.
Q. Is it a corporation, a partnership?
A. It's an LLC, and my partners are the parent company, IPS.
Q. IPS?
A. Integrated Project Services.
Q. How many employees does Somma Tech Consulting have?
A. We have two.
Q. Who are they?
A. Me and a ten -- excuse me -- I should correct that. 1099 doesn't constitute an employee, so we have

me and a woman that does our transdermal work at the present time.

Q. What do you mean does your "transdermal work at the present time"?

A. She consults in an area of transdermal delivery systems for another firm that we work for.

Q. Okay. What's her name?

A. Amanda Gotto.

Q. Say that again?

A. Amanda Gotto.

Q. Is Amanda Gotto consulting in any other litigation?

A. No.

Q. Has Amanda Gotto had any input into your analysis or report in the Digitek litigation?

A. No.

Q. And then who is IPS?

A. IPS is a company that Somma Tech is a part of. It's an engineering project management -- project management firm.

Q. In fields other than pharmaceutical?

A. They are predominantly in pharmaceutical, but they have been known to do work in other areas on the soft side; not heavy industry.

Q. I assume that they are a consulting group?

A. That's correct.
Q. Did anyone from IPS have any input into your analysis for the drafting of your report in the Digitek litigation?
A. No, they have not.
Q. I assume that you are charging the plaintiffs' lawyers for the time that you have spent reviewing material and writing your report?
A. Yes, I have. Yes.
Q. Is that right?
A. Yes.
Q. How much are you charging for that?
A. $350 an hour, Matt.
Q. I assume you are charging me for the time we spend all day today with me questioning you about your report. Is that right?
A. If you would like, yes.
Q. Well, I prefer not, but I assume you are going to. So why don't you tell me how much I am going to be charged.
A. $350 an hour.
Q. Thank you.
Do you have any idea how many bills you have already sent the plaintiffs' lawyers for your review to date?

A. Three.
Q. What's the total of those bills?
A. $40,000.
Q. How much do you have in unbilled time up to today?
A. I would say about 30,000.
Q. So, just so I'm clear, you think that the total amount of time that you have put into this review and writing to date is about $70,000?
A. No, no. In other words, as I can tell -- I have a time management system that we put in our time for. Based on that time, there is about $40,000 in billing. Okay?
Q. Okay.
A. And those invoices, we have been paid the first invoice, which was the initial retainer; but since then we have not provided -- we haven't provided the invoices on a more timely basis.
Q. So you believe that the total amount of time, the value of the time you have put into this is about $40,000?
A. That's correct, Matt, yes. Sorry.
Was that too long of an answer, Matt, just so we know going forward?
Q. No. "Yes" is good. I really like that.

You have a Ph.D. in pharmaceutical science from Rutgers; do you not?

A. Yes.

Q. Now in your day-to-day wanderings about the world including your consulting work, are you called "Mister" or "Doctor"?

A. Well, I never really paid much attention to it, but most of my clients refer to me as "Doctor," you know.

Q. Okay. Dr. Somma, have you ever --

A. That doesn't include you, by the way.

Q. Okay. So I can call you Mister?

A. No, "Russ" is good. But go ahead.

Q. In your industry experience, and I understand that that was primarily at Novartis. Is that correct?

A. That's right, yes.

Q. Did you ever work on a digoxin product?

A. I worked on a cardiac glycoside, yes, sir. I worked on Serpasil. Serpasil is in the same general class. Is it digoxin? No, sir.

Q. Is it digitalis?

A. No, sir, it's reserpine.

Q. Is it derived from the "something-lanata" plants that --

A. It's a natural alkaloid. I can't tell you if

it's from the same plant, no, sir.

Q. And is Novartis' cardiac glycoside product an IV or a solid oral base?

A. Solid oral dosage form.

Q. And what was your involvement with that?

A. Production support and troubleshooting.

Q. Okay.

A. Just for clarity, it was Ciba at the time.

Q. How did you -- How long did your duties involve that product?

A. These things came up periodically, so your responsibility was the product line. So reserpine or Serpasil in this case was the hot topic for six, eight months, and then it would go -- you would go onto the next product or problem. Is that clear?

Q. Yes. When you were working on -- was it a product that was in full commercial production?

A. Yes, sir, it was.

Q. Did you have any role at all in adverse event reporting analysis for that product?

A. No, sir.

Q. Were you at least aware that the drug is known to have a narrow toxic therapeutic window?

A. When I worked on the drug, the term "narrow therapeutic window" wasn't commonly used. It was just

a low dose drug for us, and to me that was the issue in that case.

Q. When you say "low dose drug," are you talking about the actual amount of the active pharmaceutical ingredient in the tablet?

A. That's correct.

(A discussion is held off the record.)

A. The amount of active ingredient in the dosage form. In this case, less than a milligram.

Q. And do you know what the dose strengths were of reserpine when it was -- when you were dealing with it at Ciba?

A. I would have to guess, but point-one as I recall is one of them.

Q. Do you know if they made a 0.5 milligram dose?

A. That I can reasonably say with assurance, no.

Q. When were you involved with reserpine?

A. Reserpine was back in 1976.

Q. Okay. This is long before the FDA's digoxin regulations?

A. It was around the same time, because I remember a lot of digoxin noise when I was in pharmacy school about, you know, different products; but primarily that wasn't on my radar screen at all.

Q. Did they ever put in an NDA for reserpine?
A. Yes, it was; it was an NDA.
Q. When?
A. That I don't know, sir.
Q. Did you ever have anything to do with the quality control chemistry testing of reserpine?
A. Chemistry testing, no, sir.
Q. Do you know what kind of tablet presses they used?
A. Yes, sir.
Q. What?
A. Manesty Mark II.
(A discussion is held off the record.)
Q. The difficulty that Mark, the court reporter, is having is that you are looking at me and it just makes it a little harder for him. And that's unfortunately the way this room is set up and kind of the way it has to be. Okay?
A. All right.
Q. Did Manesty Mark II tablet presses have weight control equipment on them?
A. They did, sir, yes.
Q. When they had weight control on them, did they weigh all produced tablets or just random samples?

A. Let me -- let me -- let me -- If I may, Matt. Matt, Manesty Mk II's have weight control on them. If your question is -- if your question is: Did we use those to make reserpine? Is that -- or am I jumping ahead here?

Q. Well, I asked you what kind of tablet presses --

A. Manesty Mark II's.

Q. -- presses Ciba used to make reserpine?

A. That's right.

Q. Did the Manesty Mark II's that were used to make reserpine have weight controls?

A. The ones that we owned that made reserpine, no, sir. Okay? Sorry. I was thinking of it in a global sense.

The answer is: They do have them. We didn't have it on that machine.

MR. MILLER: No, that's fine. You are doing fine.

Q. So the -- So whatever in-process weighing, measuring and hardness testing was done, was done either by a QA employee or -- and/or a press operator. Is that right?

A. That's correct.

Q. Do you have any memory of how often the QA

person came in to check thickness, hardness and weight?

A. The QA person, I don't recall, sir, no.

Q. Do you know how often the tablet press operator was expected to check samples of thickness, hardness or weight?

A. Every half hour is our custom.

Q. How much of your work in your industry experience was solid oral dose?

A. I would say 98 percent of it, sir.

Q. And you worked essentially from the conclusion of your bachelor's in pharmacy until you left private industry at Novartis or its predecessor companies. Is that right?

A. That's correct.

Q. Almost 30 years?

A. Almost, sir.

Q. Why did you leave Novartis in June of 2004?

A. I retired -- not retired. Excuse me. I resigned. Sorry about that. To be clear, I resigned. I resigned.

The opportunity came up with people I've worked with at various associations and different professional groups that it seemed to me that owning my own company was going to be an opportunity to

explore and expand and share my background. I had gotten quite a lot of airplay from work we had done. Bottom line was: I capitalized on things I had in place, left, and started my own company. That is why IPS is my partner.

Q. And what are you, about 58 years old?

A. Fifty-nine.

Q. Now, in your industry experience at Novartis and its predecessors, did you have any experience in dealing with the FDA in inspections?

A. Yes, sir.

Q. And I assume that happened over the years, FDA would come in and conduct inspections?

A. Yes, sir, primarily pre-approval inspections for drugs.

Q. Did you ever have any experience in remediating 483s or warning letters that were given to your employer?

A. 483s, sir; warning letters, no.

Q. What about establishment inspection reports?

A. I was aware of their existence.

Q. Did you ever have any experience with product recalls when you were in your industry experience?

A. Yes, sir.

Q. What was the product that was recalled?

How many recalls were you involved with? Let's put it that way.

A. I would say two, sir.

Q. Were they solid, oral dose?

A. Yes, sir.

Q. What were the reasons for the -- and can you tell me what the products were? I assume it's public knowledge?

A. Well, I think -- well, one of them was a -- a field action for a carbamazepine.

Q. Okay.

A. Carbamazepine I believe is Tegretol.

Q. Why was carbamazepine recalled?

A. It was I believe -- and, again, the recall was the key; I don't recall if it was a voluntary recall. The key was that we had found anomalies in the tableting operation.

Q. Okay.

A. And these were in hardness dose specifications.

Q. Was the recall a precautionary recall?

A. Yes, sir.

Q. Was it to the consumer level?

A. That I don't remember, sir.

Q. To the best of your memory, did you ever find

any car --

A. Carbamazepine.

Q. -- carbamazepine tablets actually in the field that failed your specifications?

A. From the best of my memory, I don't recall bringing them back. Because we primarily would depend upon our retained samples to assess what's in the field.

Q. Okay.

A. Understanding, of course, that what's in the field you have no control where it's been, so we went by retains.

Q. Okay.

A. But when they came back, we tested them.

Q. All right.

A. Right.

Q. What do you mean, "when they came back"?

A. When the samples came back from -- a complaint sample would come back, we would test those.

Q. Yes. Okay. And the ones that were tested, were they out of spec?

A. That I don't recall, sir, right now specifically, to be honest.

Q. Well, sometimes in the pharmaceutical industry you do a recall even though the product in

the field may not actually be out of spec; correct?
A. That's right. Out of precaution, correct.
Q. Okay. So what was the second recall that you had anything to do with?
(A discussion is held off the record.)
Q. And, again, I told you in the beginning, that if you don't know the answer to my question, I don't want you to guess.
A. No. I think in that particular case it would take -- it would be a stretch for me to answer the second recall question.
Q. Was it a solid oral dose?
A. Yes, it was.
Q. Do you remember what the problem was? Or why the --
A. I believe -- I believe it was dissolution, as I recall. That was -- and I think that's about as best I can do. I think -- We used to monitor levels, S1, S2 levels.
Q. Okay. When you were at Novartis and its predecessors, did you ever have -- did you ever reject batches that didn't meet the specifications?
A. I was not in that position, no, sir.
Q. Do you know whether it happened?
A. Rejection of batches? Yes, sir.

Q. Okay. And certainly out-of-spec investigations occurred from time to time?
A. Absolutely.
Q. Is that right?
A. Absolutely.
Q. Now, what -- Were you in the Manufacturing Division, the Quality Department --
A. Research and Development.
Q. Research and Development. Did you ever get involved in products that were in full-scale commercial development?
A. Yes, sir.
Q. I'm sorry. Full-scale commercial production?
A. Yes, sir.
Q. And did you spend most of your career in Research and Development?
A. I was all -- my entire career was in research and development, which included product production at some point.
Q. And I assume that's one of the reasons why one of your particular interests in pharmaceuticals is what's known as scale-up. Is that correct, sir?
A. That's correct, sir.
Q. And technology transfer?
A. That's correct.

Q. And in my plain English, the -- the science of going from research and development small batch sizes to full commercial production scale pharmaceutical manufacturing; correct?

A. That's correct. And even in simpler terms, it's simply moving it from Place A to Place B.

Q. Place A little and Place B big?

A. Or Place A little to Place B little, to minimize problems. Okay?

Q. At Page 4 of your resume, you have Publications and Presentations.

A. Uh-huh.

Q. Do any of them involve digoxin?

A. No, sir.

Q. Do any of them involve troubleshooting of oversized tablets?

A. To the best of my knowledge no, sir. I'm checking as we're going, just to make sure I'm giving you the right --

MR. MILLER: That's fine. If you need to check, go ahead and check.

A. I doubt specifically oversize.

Q. You wrote them. I didn't.

A. Yeah.

Q. Do any of them have anything to do with the

appropriate ways to get to a root cause analysis?

A. While none of them speaks to that topic by inference, I think that these types of things are tools that would be used in a root cause analysis, but they are not titled such.

Q. Okay.

A. Okay?

Q. When was the first time you met in person with somebody from the plaintiffs' lawyers group in this case?

A. I think -- I'm guessing -- No, I'm not going to guess.

Well, not to waste time, I'm thinking mid -- late May, mid May, something like that.

Q. Who has been your primary contact?

A. Meghan Johnson.

Q. I assume you spent some time with plaintiffs' lawyers either this morning or yesterday preparing for your deposition today?

A. Yes, sir.

Q. Who did you meet with with?

A. I met with Meghan and Pete Miller.

Q. And did they tell you anything about the deposition testimony of a Mr. Farley that took place in Savannah, Georgia on Monday?

A. No, sir.
Q. Did they tell you anything at all about the deposition testimony of Mark Kenny that took place in this room on Tuesday?
A. No, sir.
Q. Did they tell you anything about the deposition testimony of a Dr. Frank that took place in Philadelphia yesterday?
A. No, sir.
Q. Have you read the reports of any other experts in this case?
A. No, sir.
Q. No Dr. Semigran, no Dr. Nelson?
A. No, sir.
Q. Not Farley, Frank?
A. No.
Q. Etc., etc.?
A. No. If I had a guide, I probably wouldn't have made the mistake I told you about. Do you know what I mean?
Q. I --
A. Okay.
Q. Other than Pete Miller and Meghan, who have you talked with about this litigation?
(A discussion is held off the record.)

A. That would be the guy at Spyglass, Mark Kenny.
Q. Did you talk to him about substance or just logistics?
A. I think part of it was -- when you say "logistics," who is going to do what?
Q. Who is going to do what, here's who to call, things like that?
A. That was partly, partly --
Q. Did you talk about the substance of the litigation, what the claims were?
A. When we first met with them. Because like I said, we had been contacted and they explained to me what this was about. So I think in that particular case, there was a substantive amount of discussion, yes, sir.
Q. Did you meet with Mark Kenny in person?
A. Yes, sir.
Q. Where did you meet?
A. In Chester, New Jersey.
Q. Was there anybody else present?
A. As I recall, Sal Romano was present as well.
Q. All right. Did you keep any notes from that meeting?
A. Those I did not sir, no.

Q. And I see you have a spiral bound notebook in front of you. Is that correct?

A. That's right.

Q. Is that notes about substance, or just your ongoing logistical work in the matter?

A. Because -- actually, it's everything that I've done. If -- in other words, if I've read -- if I've read a lot of material, I'll make notes in here rather than try to make a paper copy. Or if I have a meeting, I'll put the notes in here.

I did not start this, because when I talked to the guys at Spyglass -- excuse me -- Mark Kenny, I hadn't been selected to do the job.

Q. All right. Did you bring a photocopy of your notebook today?

A. No, sir, I did not.

MR. MORIARTY: At some point today we will have to mark the notebook and make sure we get copies of the notes.

MR. MILLER: Okay.

Q. So other than Pete and Meghan and Sal and Mark Kenny, have you talked to anybody else about this litigation?

A. Well, we visited Actavis and I talked to Michael Anderton, right? So I guess that counts too.

Q. Right. And whoever else was along that day?
A. Was there -- I forget. There was a -- well, there was Michael and the guys from Actavis. I didn't talk to them obviously, but --
Q. What I really want to know is: Did you talk to anybody else about the substance of the litigation?
A. No, sir.
Q. Do you have any military service?
A. No, sir.
Q. Have you ever been a professor at any school?
A. My teaching assignment was limited to my residency for my doctorate.
Q. Do you consider yourself to be an expert in pharmacokinetics?
A. No, sir.
Q. Pharmacology?
A. No, sir.
Q. Pharmacovigilance?
A. No, sir.
Q. Do you consider yourself to be an expert in the regulatory aspect of the pharmaceutical industry?
A. I'm familiar with the regulatory aspect in the amount that it requires me when I do my job, because it's a regulated industry. Am I an expert? No, sir.

Q. Are you an expert in quality assurance?
A. No, sir. And, again, where it overlaps into what I do:
Q. Okay. And I asked you I think a little bit before: You don't consider yourself to be an expert in quality control chemistry?
A. No, sir.
Q. Have you ever looked at the Digitek detailed patient labeling?
A. Yes, sir.
Q. Have you ever looked at the United States Pharmacopeia monograph regarding digoxin?
A. Yes, sir.
Q. Did you ever look at the USP monograph about digoxin as part of your work in industry?
A. No.
Q. Have you ever looked at at the USP monograph on digoxin before your litigation consulting in this case?
A. There was no reason to. No, I did not.
Q. Now, let's get back to your report.
Exhibit 52, I believe it is, Appendix A. Would it be safe for me to say that a lot of what you relied on for your analysis in this case was FDA Form 483s and warning letters?

A. I wouldn't say predominantly, no. I think I looked for more content in technical information, batch records, investigations, internal documents. That's my -- my -- what I -- customarily how I do that.

Q. All right. In Appendix A, the only batch record I see listed is seven -- it should be 70924A. You actually have a typo here.

A. Yes.

Q. It's the second item from the end.

A. Yeah.

Q. Is that the only batch record you reviewed?

A. No, sir.

Q. What other batch records did you review?

And while you are looking for those, are these batch records that you received subsequent to drafting your report?

A. No.

Q. So you reviewed other batch records, but did not put them in Appendix A?

A. That's correct. I think because -- Well, let me find it first so I understand what you are talking about.

71005A.

Q. 71005A?

A. 5A.
Q. Okay. What else?
I'm sorry. I have a question about that.
Is that the complete batch record?
A. That I couldn't say.
Q. Does it have the mixing information?
A. It has the procedures necessary to make the blend and the tablets. The M -- M --
Q. Well, wait a minute. Just answer my question.
A. Yeah.
Q. Does it having mixing information with the weighing and measuring of the excipients and the active pharmaceutical ingredient?
A. Yes, sir.
Q. It has the blending information?
A. Yes, sir.
Q. Does it have the chromatography for the blend uniformity samples?
A. It has the results. It doesn't have the raw data.
Q. All right. Does it have the in-process tableting data, such as the QA and the operator checks?
A. Yes, it does, sir.

Q. Does it have the results of the quality control testing, such as assay and content uniformity?
A. Yes, it does.
Q. Does it have the packaging information?
A. It looks like it does, sir, yes.
Q. Okay. What other batch records did you review besides 70924A and 71005A?
A. Those are the only two I looked at before I wrote the report.
Q. Do you know how many batches were included in the recall?
A. I don't recall, sir.
Q. Do you know that we have produced at least 152 batch records to the plaintiffs' lawyers in this case?
A. I didn't know that number. I would imagine the product has a lot of batch records, yeah.
Q. Did you ask to look at any more batch records?
A. Yes, I did.
Q. And what happened with that?
A. I -- subsequent to my request, they put more on the site for me to look at, yes.
Q. They put more on the site?
A. We have a -- there is a database that some of

this information be placed on for me to access. And I was able to go in there and take a look.

Q. Did you?

A. Yes, sir.

Q. Okay. My question was: What other batch records did you look at besides 70924 and 71005.

So what batch records did you look at on this site?

A. I don't remember the numbers, to be honest with you, sir.

Q. How many batch records did you look at?

A. It must have been at least three.

Q. Were 152 batch records available on the site?

A. That I don't know, sir.

Q. What's the web address for the site?

A. It's Crivella.com, the W -- the web address.

Q. That's good. Is this a website for which you needed a password?

A. Yes, it is.

Q. Did you make note anywhere in your notebook of what other batch records you reviewed on line?

A. No, sir. You will find these two that we just talked about.

Q. All right. Other than what's on Exhibit -- I'm sorry -- Appendix A, what else have you reviewed?

A. I've looked at everything that's on these drives.

Q. You are pointing to a little white box that presumably has a thumb drive in it?

A. Several thumb drives, sir.

Q. Are they -- is there different material on those two thumb drives?

A. Actually, yeah, there's three.

MR. MILLER: Three.

A. And there is documents that were pulled from the site and -- on two of them, which are these two.

And I'm not clairvoyant. I have them written on the back. I see you looking at me.

And the third one is e-mails that you have asked to see.

Q. All right. Now, are those thumb drives duplicates that I can take, or do they have to be duplicated?

A. No, sir, these are -- you requested these and these are for you.

Q. Okay. Thanks for the little white box, too. I appreciate it.

A. Well, I realize you wanted yes or no, but the answer is: You'll lose them, believe me. So I put them in a box. Sorry.

Q. Could you give them to Mark, please?
A. Sure. Mark.
Q. That Mark.
A. There you go.
MR. MORIARTY: Mark, mark it.
(D-51A, White Box Containing Three Thumb Drives marked for identification.)
Q. Dr. Somma, is 51 -- Exhibit 51A the little white box with the three thumb drives on it that we just discussed?
A. Yes, sir.
Q. Okay. Can I have that?
A. Sure thing.
Q. And just so I make sure I understand what is on it, on those thumb drives, is that material in addition to Appendix A?
A. Yes, sir. And the drafts.
Q. Drafts of your report?
A. And -- yes.
Q. You are very organized. I appreciate that.
A. Well, you made a pretty good list, Matt, so...
Q. I see at the end of Exhibit A that you reviewed the depositions of Richard Dowling, Phyllis Lambridis, Dan Bitler and Scott Talbot. Is that

correct?

A. Yes, sir.

Q. Did you read the whole deposition? They're kind of long?

A. They're really long. I went through them and I got a -- I started skimming stuff, looking for pieces.

Q. Did you make notes anywhere of things that any of those four witnesses said --

A. Yes.

Q. -- that you disagreed with?

A. Disagreed?

Q. Disagreed.

A. I would have to actually look at all my notes. I made notes about things they said. Whether I disagreed or agreed, I can't say yes or no.

Q. Okay. We'll look at your notes later. If I have time for that, I'll go back to it.

A. Okay.

Q. Did you ever look at the ANDA?

A. Yes, sir, I did.

Q. Is that on Appendix A or --

A. That's on the jump drives. Excuse me. Thumb drives.

Q. Now, when you are -- what kind of things is

SommaTech asked to do in your consulting practice?

A. Like I -- just to make the connection, when I left Novartis, my reputation was for scale-up and fixing production problems.

Q. Okay.

A. So as soon as we put the shingle out, we started fixing people's problems. My expertise in several areas, that was people -- the network knew I was out about; I got contacted.

Q. All right. Have you ever been consulted as part of SommaTech for an over-thick or overweight tableting problem?

A. Yes, sir.

Q. Go back to your industry experience. And I'm sorry for jumping around.

A. That's okay.

Q. Did you ever have overweight or over-thick tableting problems at Novartis?

A. Not that I recall.

Q. Are you -- is the identity of your consulting client with the double -- or the overweight or over-thick tableting problem, are you able to discuss that consulting?

A. To be honest, just so -- the way consulting works in our business, because we sign CEAs.

Q. Okay.
A. Yeah, so I --
Q. All you have to do is say "No, I can't discuss it."
A. Okay. I want to try to make sure you know: We are not a mom and pop operation, so --
Q. I understand. So what was the specific tableting problem that this consulting client had?
A. That tablets which were oversized essentially got into distribution.
Q. All right. Did you ever figure out how many --
A. No.
Q. -- oversized tablets had gotten into distribution?
A. No, sir.
Q. Is that consulting engagement closed?
A. Absolutely, sir. In fact, in that particular case, for clarity, we were consulting on a different issue, on a different product, and this came about and we were asked. Okay?
Q. Okay. What did you look at once they said, "We have this oversized tableting problem;" what did you do, what documents did you look at, who did you talk with to try to figure out what the problem was?

A. We did a -- again, to be clear, our involvement in this was not heavy.

They asked us to look. We looked at the batch records in this particular case, which are similar to what we looked at in this situation.

Q. Okay.

A. And we did not see any anomalous behavior.

Q. How many -- go ahead.

A. Excuse me. I'm fine.

Q. How many batch records did you look at as part of that consulting engagement?

A. In that particular case, I looked at the batch in question or the batch they said they had the problem with, and a previous batch, you know, what was the batch before that and what was the batch after that. Only because that's my -- my approach to things.

Q. Okay. And, you know, I don't remember off the top of my head what Batch 71005A was. Do you remember when it was --

A. I'd have to look.

Q. -- compressed? I mean, maybe you remember off the top of your head that it was a preceding --

(A discussion is held off the record.)

Q. -- or following 70924?

A. I could probably give you a better sense of that as soon as I look at the date. My --

Q. If you just tell me the date, that's fine?

A. The date on this is December 17th, '07. This is during the compression sheet.

Q. Okay. So it was close in time to 70924?

A. Yeah, but I wouldn't say that it was like right next to each other.

Q. That's fine. So for that consulting client, they had produced some extra-thick tablets. Is that right?

A. That's correct.

Q. And some of them, were they verified to have made it out into the marketplace?

A. Yes, sir.

Q. Was there a recall involved?

A. Yes, sir. Again, as that started to -- just so you got a full disclosure, as that started to gather and evolve, they were aware of it, they were going to take action, and voluntary subsequent to that the thing really took on a life of its own. Okay?

Q. Okay.

A. We were not involved in that aspect. Just want to give you a sense of it, so you don't assume I was sitting there at the helm. Okay?

Sorry to babble on, but I didn't want you to waste your time going down that street, you know.

Q. But when you looked --

A. Right.

Q. -- at the batch records --

A. Right.

Q. -- you didn't see a problem?

A. No, sir.

Q. You didn't see anything like a validated process that was out of control?

A. You see, your first step is: You look at the batch record. I didn't see anything. Customarily the next thing you would do is look at the validation. I didn't do that. Okay? So I don't make that assumption, I don't make that leap until I look at it. Okay?

Q. All right. I'd like you to look at Exhibit 52?

A. Yes, sir.

Q. Third full paragraph.

A. Yes, sir.

Q. Oh, I'm sorry. The very end of the first full paragraph. You were an "invited investigator trainer and liaison for the FDA on various projects and initiatives"?

A. Yes, sir.
Q. What projects and initiatives were those?
A. They had a project to train their field investigators who were not that knowledgeable in industry -- common industry practices.
So at the time, it was customary for the field officers or people in the Compliance branch to identify people in industry to come in and teach.
Q. Okay. And what did you teach?
A. On matrix tablets.
Q. What are matrix tablets?
A. Matrix tablets is a term that's used in the industry to define a timed-release tablet, a sustained release.
Q. Third full paragraph. You refer to yourself as a "recognized industry subject matter expert."
What do you mean, "recognized"?
A. That people come to me and employ my services in technology transfer.
Q. Next full paragraph, you're talking about some publications. Are you sure that those publications are peer reviewed?
A. Yes, sir.
Q. Okay.
A. I have to change glasses. Excuse me.

Q. Go to Page 2, please. In the Introduction sentence -- I'm sorry. In the Introduction section, the first sentence and the last sentence refer to "our review."

A. Right.

Q. Who is "our"?

A. I have to note that when I write things in general, it's my habit to write in the "we, our." Simply because as a firm, I write that. It should be -- I hope I'm making sense. It's SommaTech's opinion, the answer is that's how I write things.

If it's a mistake -- in this case -- I would say it's a -- it's a grammatical mistake.

Q. That's fine. This is all your work?

A. This is my work, sir.

(A discussion is held off the record.)

Q. Second full paragraph, the last sentence, you are talking about "the final distribution of a batch within which a pharmacist who was dispensing the product in the field reported "double-thick" tablets."

Do you see that sentence?

A. Yes, sir.

Q. The next paragraph starts with the reference to Batch 70924. Do you see that?

A. Yes, sir.

Q. Are you talking about two different batches?
A. No, sir. I'm not.
Q. So do you believe that a pharmacist somewhere in the United States found a double-thick tablet that was made as part of Batch 70924 in November of 2007?
A. That's -- That's my understanding, yes, sir.
Q. I would like you to dig through whatever documents you need to dig through to find that for me, because that would be a revelation.
MR. MORIARTY: And, Pete, if you know what he is referring to, by all means help him to speed this up.
MR. MILLER: All right, I will.
(A discussion is held off the record.)
A. I realize I'm wasting your time. It's going to take me a bit. I thought I had it here.
Q. Do you remember what the content of that exhibit is?
A. It was a -- as I recall, it was --
Q. No, wait. Yes or no. Do you remember it enough to answer questions about it?
Because I know what you are talking about.
A. Okay.
MR. MILLER: I would object to him answering off of memory.

A. Yeah, I think --
MR. MORIARTY: Maybe he has enough memory to answer it. That's what I asked him.
A. Right.
MR. MILLER: That's what I objected to.
Q. He objects to your memory.
MR. MILLER: No. I object to your question.
Q. Do you have enough memory of that exhibit to answer questions about it?
A. Why don't you ask me the question.
Q. Sure.
A. And then you know what? If I can't accurately answer it, I'll answer yes or no.
Q. Do you know whether that was found by a pharmacist or somebody at a nursing home?
A. As I recall it was a pharmacist. Whether he was at a nursing home, I don't recall.
Q. Do you know if it was in a blister pack or in a bottle?
A. That I don't recall.
Q. Do you know if it was weighed?
A. That I don't recall either.
Q. Do you know if it was measured?
A. No.
Q. Do you know if it was ever returned to Mylan

or Actavis?

A. I believe it was part of a complaint.

Q. Was it ever returned to Mylan or Actavis?

A. Not to my knowledge.

Q. Was the e-mail that you looked at an internal Mylan e-mail?

A. I don't remember the format.

Q. Was there actually correspondence from the person who supposedly saw this directly to Mylan or Actavis?

A. The person who found it?

Q. Yeah.

A. No, sir. That's -- that I do remember.

Q. Okay. Would you agree with me -- you know what a blister pack is; right?

A. Absolutely, sir.

Q. Would you agree with me -- I'm sorry. Let me ask another question first.

Let's assume it was in a blister pack. Do you know whether the blister pack was ever opened so that they could actually inspect the tablet?

A. I couldn't answer that, because I don't remember it being in a blister pack either.

Q. But if -- if it was in a blister pack and they didn't remove it to weigh or measure it, would

you agree with me it would be extremely difficult to see through the pack as to what the actual size was?

MR. MILLER: Objection.

A. If you are asking me -- if I was asked to measure the tablet that was inside of a blister pack, my answer to that would be that's impossible to do accurately.

Q. Okay. If you were asked to do an investigation of an incident where somebody reported that there was a double-thick tablet, wouldn't you try to have some communication with the person who supposedly saw it?

Let me go back and ask a different question.

A. Okay.

Q. Okay. I'll withdraw that question.

Let's assume that one of your consulting clients calls you and says, We think we may have released some extra-thick tablets. We have a report, a third-hand report, of somebody in Massachusetts at a nursing home who may have one. We want you to look into it." Okay? Now, let's go from that premise.

Would you try to communicate with the nursing home person in Massachusetts who supposedly saw it?

MR. MILLER: Object to form.

Q. Yes or no?

A. I would ask to see the sample first.
Q. Okay. You'd ask to see the sample?
A. Yes, sir.
Q. And if it was in a blister pack, would you open the blister pack?
A. Yes, sir.
Q. Would you weigh it? The tablet.
A. Yes, sir.
Q. Would you measure it?
A. Yes, sir.
Q. Would you consider submitting it to a lab for testing for its active pharmaceutical ingredient content?
A. Customarily I would, because that was how I did things, yes, sir.
We didn't -- I wouldn't call the guy at the nursing home. We didn't get that far.
Q. Well, if you couldn't return the sample, would you call the person at the nursing home to find out what they actually did to analyze it?
A. I think, if I understand -- maybe I'm having trouble with understanding the question. I'm not trying to be stupid.
They found it. They reported it, but they didn't send it back. Did I get that? Is that the

question?

Q. Yeah. But if it wasn't weighed, wasn't measured, wasn't taken out of the blister pack, we don't even know who this person was, what their qualifications were, whether they're a pharmacist, a nurse or ward secretary, that isn't a very reliable report for you to go on as a pharmaceutical investigator; is it?

MR. MILLER: Object to form.

A. You would have to determine that person's credentials in the building, yes.

Q. Would you agree with my statement that's not a very reliable report if none of that was done?

MR. MILLER: Objection.

A. I would say yes, that you would have to have more reliability.

Q. Dr. Somma, since we are going to be going all day, we do take periodic breaks. I'm willing to keep going. But if you need a break now, I'm about to change subjects. Okay?

A. Okay. Can I stand up, then?

Q. Sure, you can stand up.

MR. MILLER: All right. We'll take a break.

Is that what we're doing?

A. Is that okay?

Q. I don't need a break. Do you want to just stretch your legs and sit right back down, or do you want a general break?

A. I was going to hit --

Q. Then let's take a break.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 9:37 a.m. This is the end of Tape 1.

(A discussion is held off the record.)

MR. MORIARTY: This is the first witness that I've deposed who's said that he has seen that document. If you sent that to your other experts, I need to know. Because no one else has mentioned that document.

I don't need to know today.

MR. MILLER: Right. Okay.

MR. MORIARTY: I don't want you to guess.

MR. MILLER: Yes. I need to confirm and get back to you.

MR. MORIARTY: I just need to know before we take any more depositions.

MR. MILLER: Fair enough. I will get back to you.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 9:45 a.m. This is the beginning of Tape Number 2.

Q. Dr. Somma, I'd like you to go to Page 7 of your report, Exhibit 52, please.

A. Okay.

Q. The first full paragraph is referring to dedusters and metal detectors. Is that right?

(A discussion is held off the record.)

A. I'm sorry, Matt. May I have the question again?

Q. All I asked is: Are you talking about dedusters and metal detectors --

A. Yes.

Q. -- in that paragraph?

Is it routine in the pharmaceutical tableting process to have dedusters and metal detectors?

A. Yes, sir, very common.

Q. Why?

A. The deduster -- the first -- the deduster is to take off, you know, loose powdered material, makes it easier to go through, make a cleaner product in the packaging, less contamination of bottles, cleaner operation.

Metal detectors are to pick up any metallic material which may come off as a piece of a machine, broken part, small things. And a metal detector is to assure that that does not happen.

Q. Did they use metal detectors at Novartis in the tableting process?

A. Yes.

Q. Okay. Now I'd like you to go to the next paragraph. You're talking about sample frequency.

Do you see that?

A. Yes, sir.

Q. I want to ask you about that.

Would you agree with me that you cannot chemically test every tablet in a production line, because you would have nothing to sell to the consumers?

A. That's correct, sir.

Q. So it is routine in the pharmacy industry to do a couple of things. One is in-process sampling of weight, thickness and hardness and appearance. Is that right?

A. That's right.

Q. And then when you have finished tablets, a certain sample of them are sent to the Quality Control lab for assay and content uniformity testing?

A. That's correct.
Q. Is that right?
A. That's correct.
Q. Now -- And typically does the ANDA contain information about how many times per half hour, hour, whatever the sequence is going to be, for the in-process testing?
A. Yes, the ANDA does, yes.
Q. And the ANDA would contain information about the size of the samples of finished tablets that would be sent to QC for assay and content uniformity?
A. Yes, sir.
(A discussion is held off the record.)
Q. So the FDA approved the ANDA for this product; did they not?
A. Yes, sir.
Q. As a matter of fact, I hand you Exhibit 6, tell me if you have seen that before?
A. Yes.
Q. First, have you seen it before?
A. Yes, I recall seeing it.
Q. It's the FDA's letter to Amide, the predecessor to Actavis, approving the ANDA; correct?
A. Yes, sir.
Q. And presumably FDA was fully aware from the

contents of the ANDA as to what the sampling plans were?

MR. MILLER: Object to form.

A. The sampling plans were in the ANDA, correct.

Q. All right. Are you familiar with current Federal Regulations 211.110C about sampling?

A. No, sir.

Q. All right. Do you know of any regulation in the CFR that's part of the pharmaceutical manufacturing guidelines which specifies either the frequency of in-process testing or the number of tablets that are analyzed during production runs?

A. As I recall, I am not an expert in that area, but as -- as I recall, you look to things like the USP for guidance on sampling and testing.

Q. Okay. Were the Amide and Actavis in-process sampling plans in the batch records?

A. As I recall they were, sir.

Q. Did the FDA have every opportunity to look at those and comment upon them if they wished between 2004 and 2008 when they did their inspections?

A. Yes, sir.

Q. And have you seen any warning, observation or other comment by FDA in the 483s or the warning letters to the effect that Actavis' in-process

sampling plans were inadequate?

A. Can I just refer to one of these?

MR. MILLER: Certainly.

A. What I wanted to check back, to answer your question now, is you asked specifically to FDA input, and I double checked; and to my knowledge -- to my recollection, they had no problem with the sampling frequency.

Q. Okay. And I skipped. I didn't ask you about this. But, you know, certainly the blend uniformity sampling plan: The number of samples, the type of sampling they used, the locations in the blender, that's all in the ANDA; is it not?

A. That information was in the ANDA. What I -- and it looks like these things have continued to be worked on and progressed at Actavis.

Q. Okay. And they are in the batch records; are they not?

A. They sure are, as planned deviations, which means it is over and above what they had indicated they wanted to do.

Q. Okay. All right. And I don't want to talk about blend uniformity investigations right now. But as far as the sampling plans are concerned, did you ever see any FDA observation warning letter or 483

criticism of the actual blend uniformity sampling plan itself?

A. Looking, again, at what I just looked at, I just -- my -- my answer would be no.

Q. And then the finished product testing; the number of finished products they sent for assay or content uniformity, that was in the ANDA and in all the batch records. Is that correct?

A. That's correct.

Q. And have you seen any FDA warning, observation, criticism, regarding the finished product testing sampling plan?

A. I have not, simply because Actavis very diligently followed USP requirements, which are a minimum standard here.

Q. Now let's go back to your report.

A. Uh-huh.

Excuse me, Matt. Do I need to hand you back these things?

MR. MILLER: No.

Q. No. Actually, put them on that bigger stack there.

A. Oh, okay.

Q. I'd like you to look at -- What I did is I took your references in your Appendix A of your report

and I created a binder. And I did them by the numbers in order of your appendix. Okay?

A. Okay.

Q. So I'd like you to look at your Reference Number 4.

A. Which would be Methods For Drug Substance and Drug Products From the ANDA?

Q. Yes. Was this validated?

A. All of their methods were validated.

Q. All right.

A. Yeah.

Q. I don't see anything -- Do you see anything in the FDA regulations that indicates that there is a mandatory time period in which you need to re validate a particular process?

A. That really depends on the firm's approach to things. And, again, I'm not trying to be vague. FDA gives a firm the ability to operate their business in their own best interests. And that has to be done by an internal review.

So basically I'm answering the question: FDA doesn't say you have to do this every year or every six months.

Q. Okay.

A. That's been my experience.

Q. I didn't see anything in your report to indicate that the test methods contained in Reference 4 of your report were no longer valid in 2006, 2007 or 2008.

A. No.

Q. Is there anything in your report about that?

A. No, sir.

Q. So I assume you have no opinion to a probability to the effect that these were somehow not valid in 2006, '07 or '08. Is that right?

A. My opinion in that case is that they were valid, yes, sir.

Q. All right. So let's go back to your report.

A. Yes, sir.

Q. Page 5. You have a comment here.

A. Yes, sir.

Q. -- in the last paragraph before Packaging, it says, "We did not consider the sample frequency (every hour) used during the compression phase of the manufacturer to be adequate."

Do you see that?

A. Yes, sir, and that is the error that I wanted to bring up.

Q. All right. Well, I'll get there.

A. Okay. You know, Matt, because I know I'm not

supposed to ask you questions, but what page are you on again?

Q. Seven.

A. Oh, I'm looking at Five.

MR. MILLER: You said Five.

Q. Sorry. Well, wait a minute. Wait a minute. I'll -- I'll fix this.

Let's go back to Five.

A. Okay.

Q. At the end of the first paragraph on that page, you refer to "These tests are conducted on an hourly basis."

Do you see that? On Page 5. Last sentence, first paragraph.

A. Yes, sir; yes, sir.

Q. And then at Page 7, you were critical of the sample frequency because it was only every hour; correct?

A. Correct.

Q. All right. Have you looked back at the records?

A. Yes, sir.

Q. And you recognized that its QA comes in every hour. Is that right?

A. That's correct, sir.

Q. And the tablet press operator checks every 30 minutes?
A. Yes, sir.
Q. Correct?
A. Correct.
Q. So within the space of an hour, there are actually three checks. Is that right?
A. With counting the QA, yes, sir.
Q. Yes. All right. So if we were to dig back into Mr. Bitler's report, that is Plaintiff's Exhibit 16, we would find --
MR. MILLER: I don't believe you have handed him that.
THE WITNESS: Oh, okay.
MR. MORIARTY: I haven't. He has it in his material.
Q. Would you like your own copy of it, or can we refer to --
A. Just to be clear, that's the deposition?
Q. No. Your Reference 15 -- I'll just hand this to you.
A. Thanks, Matt.
Q. I've even flagged the pages.
Your Reference 15 is Dan Bitler's report, which is Plaintiff's Exhibit 16; correct?

A. Yes, sir. Okay.
Q. And if you go to Page 12, and the page numbers are handwritten, and I flagged one of them for you.
A. Oh, I got you. Yes, sir. Go ahead.
Q. The operator checks for Press 67 are at 7:45, 8:15 and 8:45; correct?
A. Yeah, I'm still looking for the press number.
Q. It's on the preceding page, actually. You see this is Page 2 of 5?
A. Got it.
Q. The press number is on Page 1 of 5.
A. Okay. I got it. Okay.
Q. Yes.
A. And yes, 7:45 and 8:15, yes.
Q. Okay. And then if you go to Page 20, which I've also flagged for you, these are the QA checks, same press, 7:20 and 8:20; right?
A. One hour, at one hour.
Q. So what is the correction that you want to make to your report?
A. Well, the correction is what I had -- my comment was that every half hour I thought was the operator -- every hour was the operator testing. So it should be every half hour.

Q. All right. So with a sampling frequency of three times in an hour, you'd agree with me that that is adequate in-process sampling; correct?

A. Three times in an hour is a good level of sampling, yes.

Q. Do you know what the application integrity policy is?

A. No, sir.

Q. Are you generally familiar with any regulations promulgated by FDA regarding what they expect in the way of accuracy and honesty in pharmaceutical records, pharmaceutical manufacturing records?

A. No, sir. I was -- I always assumed that it was accurate based on our requirements internally. I didn't realize it was a regulation, no, sir.

Q. Well, what do you think FDA would have done to Novartis, for example, if it found falsified data in a batch record?

A. Falsified?

Q. Falsified.

A. Well, my only experience there was, you know, a contractor we had used. The answer to your question: It's severe.

Q. It's severe. Okay. In other words, you --

you assume that these records are supposed to be accurate and reliable and honestly done; correct?

A. Yes, sir.

Q. In all of your review of this material, did you see any FDA Form 483, any FDA warning letter or any comment in the establishment inspection reports that found that the company had falsified any documents or data?

A. No, sir, I did not see anything as far as falsification.

Q. All right. So I assume that as you reviewed the material, you did not have any reason to question the accuracy of, for example, a batch record --

A. No, sir.

Q. -- or an annual report?

THE WITNESS: Sorry, Mark.

A. No, sir. When I read this, my understanding was that this was accurate and true.

Q. All right. Now, in that stack in front of you --

A. Yes, sir?

Q. -- those exhibits were marked the other day, and they are actually in their numeric order. So if you go towards the bottom of the stack. I want you to look for Exhibits 63 and 64. Okay?

(A discussion is held off the record.)
A. Sixty-three, is this correct?
Q. Yes. And 64 would be right behind it?
A. All right. Chapter 10.
Q. I want you to look at 64 first.
A. That's Chapter -- I'm sorry? Correct.
Q. Yes. Have you ever seen this before?
A. Regulatory Procedures Manual, no. I'm aware of its existence. Have I looked at this? No, sir.
Q. Do you know that this is a document of FDA's?
A. Yes, sir.
Q. I would like you to turn in Exhibit 64 to Page 10-7.
A. Okay.
Q. Section 10-2-4, Procedures. All right?
A. Yes.
Q. The first sentence there says, "Warning Letters are the principal means by which the agency provides prior notice of violations and of achieving voluntary compliance."
Do you see that?
A. Yes, sir.
Q. Do you agree with it?
A. Yes, sir.
Q. Later in that -- in that opening, it says,

"Prior Notice may be provided by means of a civil suit, administrative action or other less-formal ways, including the following."

Number 2 is the issuance of a 483. Is that right?

A. That's what -- yes.

Q. And Number 3 is "Discussion with management by an FDA investigator, documented in the EIR"?

A. Yes, sir.

Q. Is that right?

A. Right.

Q. So if I'm reading this correctly, and you tell me if you agree, according to FDA's own manual, they consider a 483 and an EIR less formal than a warning letter. Is that right?

A. My personal -- my personal opinion, yes. I would agree with that.

Q. All right. So let's now turn to Exhibit 63.

A. Okay. Chapter 4.

Q. I want to go to the second page, Page 4-2.

A. Okay.

Q. Fourth full paragraph.

A. "FDA is under no," is that it?

Q. Fourth full paragraph. So it's the next one.

A. Okay.

Q. "A warning Letter is informal and advisory."
Do you agree with that?
A. Well, I never -- we never dealt with them as an informal thing. To me it's pretty serious stuff. But if that's their opinion, fine.
Q. Okay. "It communicates the agency's position on a matter, but it does not commit the FDA to take enforcement action."
Do you agree with that?
A. That has been my experience, yes, sir.
Q. All right. And the last sentence says, "For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued."
Do you have any reason to disagree with FDA's comment on that?
A. There is no reason for me to disagree, no, sir.
Q. Do you have an expertise on what a "final agency action" means?
A. Only in a limited sense on a particular client that we have now; okay?
Q. You can put those back in the stack. I'm done asking you about those.
A. Okay. Okay.
Q. I'd like you to go to your Reference 18,

which is a 483 from the inspection of March 18 through May 20, 2008.

MR. MILLER: That's the EIR. I think he's asking about the 483.

(A discussion is held off the record.)

A. 3/18/2008 to 5/20/2008; correct, Matt?

Q. Yes, sir.

A. Okay.

Q. Go to Observation 2.

Do you know what the FDA's Turbo software is?

A. No, sir, I don't.

Q. If you look at Observation 2, the first thing that it says is "Drug products failing to meet established specifications and quality control criteria are not rejected."

Do you see that statement?

A. Yeah, I do, yes, sir.

Q. Is that a restatement of a regulation?

MR. MILLER: Object to form.

A. I don't think that's a restatement. It sounds like it's an opinion. But, again, I'm not -- I'm not an expert in the verbiage of the regs. I'm not -- it seems like it's an opinion.

Q. Did you ever read the deposition of a Quality Assurance person in this case by the name of Chuck

Koon?

A. No, sir.

Q. Well, what Mr. Koon said is that the statement I just read to you is essentially spit out of something called the FDA's Turbo software as a regurgitation of a regulation, and that what follows under the phrase specifically is the actual factual observation made by FDA at the time of their inspection.

Do you have any reason to disagree with him on that?

MR. MILLER: Object to form.

A. No, sir.

Q. Have you ever looked at the FDA's definition of the term "adulteration"?

A. Yes, sir.

Q. Is it something that you reviewed in your preparations for opinions in this case?

A. I looked at it because -- you know, like I said, I'm not an expert in regulatory stuff, so I made sure at least I had an understanding of it, yes, sir.

Q. All right. I would like you to look in that stack and see if Exhibit 39 is in it.

(A discussion is held off the record.)

Q. Is it there?

A. Yes, sir.
MR. MORIARTY: Pete, do you still have your own or do you need an extra?
MR. MILLER: I've got my own.
Q. Okay. Dr. Somma, have you seen this Exhibit 39 before?
A. I don't -- I don't recall seeing it like this, sir. Was this part of something else?
Q. I'm just asking if you have seen it.
A. Not -- no, sir.
Q. All right. This is a printout from the FDA's web -- website in a section called "Facts About Current Good Manufacturing Practices."
Do you see that at the top?
A. Yes, sir.
Q. All right. I first want you to go under "What are cGMPs" and go to the second full paragraph.
A. Okay.
Q. It says there "The cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods and testing procedures."
Do you see that?

A. Yes, sir.
Q. Do you agree with that?
A. Yes, sir.
MR. MILLER: Objection to form.
I'm sorry.
MR. MORIARTY: I'm not sure how that can be objectionable to form, when I say "did you agree with it."
And by the way, Mark, the court reporter, when I say cPMG the C is small, the G-M-P are all capitalized.
THE REPORTER: Thank you.
Q. Let's go to the second section, which says, "Why are cPMG's so important?" The second -- I'm sorry. The third sentence says, "In most instances, testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used by patients rather than be destroyed by testing."
Do you agree with that?
A. Absolutely.
Q. Now, let's go down to the fourth section, entitled "If a manufacturer is not following CGMPs, are drug products safe for use?" And the first two

sentences there talk about what adulteration means. Is that right?

A. Yes, it does.

Q. And then the third sentence says, "It does not mean that there is necessarily something wrong with the drug."

Did I read it correctly?

A. Yes, you did.

Q. Do you agree with it?

A. I think -- in this particular case, I think everything has to be taken in balance, unfortunately. I think you have to look at the whole subject. This is true on balance if everything else is correct. That's all I'm saying.

Q. So in general, and I'm not referring specifically to Digitek right now. I'm saying, in general, you agree with the FDA's statement about that?

A. If everything else is in place, yes, sir.

Q. All right. Go to the next paragraph. About two-thirds of the way down it says, "The impact of cGMP violations depends on the nature of those violations and on the specific drug involved. A drug manufactured in violation of cGMP may still meet its labeled specifications and the risk that the drug is

unsafe or ineffective could be minimal."

Do you agree with that?

A. It has been my experience, sir. That doesn't negate the firm -- or the firm in this case being subject to regulatory scrutiny. That's also my experience, yeah. Okay?

Q. So if I understand what the FDA is saying on their own website, essentially "adulteration" does not mean necessarily that the end product that gets to the consumer is defective. Is that true?

MR. MILLER: Objection to form.

A. That adulteration is a correct statement when all of the other moving parts making a product are correct, yes.

Q. I need you to answer my question.

A. I got you. Okay.

Q. If I understand what FDA is saying in this website, "adulteration" does not necessarily mean that the end product in the hands of the consumer is defective or out of its specification. Is that correct?

A. That would be my experience, yes, sir. Sorry.

MR. MILLER: You're fine.

Q. Okay.

A. Are you done?
Q. If you could just put it back on the stack or in the stack. We'll clean up in a few minutes.
I'm handing you what's been marked as Exhibit 1. Have you ever seen this process validation report before?
A. I have seen a process validation report, but not for this strength.
(A discussion is held off the record.)
Q. All right. Exhibit 1 is the process validation for the 125 microgram product; correct?
A. Correct.
Q. Do you know which process validation report you saw?
A. 0.5 milligram, or 500 microgram.
Q. Do you have any memory of when that ceased to become a commercially produced dose by any manufacturer?
A. No, sir.
Q. Okay. Here's Exhibit 2.
A. Okay.
Q. This is a process validation report for the 250 microgram product. Have you ever seen this before?
A. No, sir.

Q. Do you have any -- and these would have been the kind of things done in advance of submitting the ANDA to the FDA for approval of the product; correct?

A. No, sir. Customarily validation is done once submission is made. Depends on company policy. There is no requirements.

Q. Okay.

A. My experience.

Q. But these are the validate -- what is validation?

A. Validation is to confirm that everything that has been put in place: Specifications, systems, quality approach, is going to work once you -- once you make the product, and reliably so. Customarily validation is done three times. The current practice is it's through the entire product life cycle. Okay?

Q. All right. Would you agree that "Validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes"?

A. I will agree with that, and further --

MR. MILLER: Go ahead.

A. And further, that today it's assumed that it meets these requirements through its entire product

life cycle.

MR. MILLER: And Matt, to keep the record complete: You were reading from a document. Can I ask what document you were reading from?

MR. MORIARTY: It's my own research document.

A. Right. I've heard that statement before.

MR. MORIARTY: If it was a published source I would be happy to tell you, but I don't know where it's from.

MR. MILLER: Got it.

A. Vaguely familiar, though, Matt. Very good.

Q. Can you see if Exhibit 46 is in that stack?

A. I sure can.

(A discussion is held off the record.)

A. Okay.

Q. This is an article coauthored by one of the other plaintiffs' witnesses in this case, Mr. Farley.

Have you ever seen this article before?

A. No, sir.

Q. And just so you know, one of the co- -- the coauthor, Mr. Brooks, is a lawyer; okay?

Go to the last sentence of the first page, please.

A. Okay.

Q. It says, "The FDA's acceptance of submitted

procedures is evidence, not conclusive proof, of the reasonableness of the company's manufacturing practices and procedures."

A. I'm sorry, Matt.

Q. Do you see that?

A. I'm sorry, Matt.

Q. I'd like you to go to the very bottom. Let me have it back. It's possible it didn't copy this.

Yeah, right there, the last sentence on that page.

A. Okay. The FDA's regulation?

Q. No. I'm going to start over. The last sentence on the page.

"The FDA's acceptance of submitted procedures is evidence, not inclusive proof, of the reasonableness of the company's manufacturing practices and procedures."

Have I read that clause accurately?

A. Yes, sir.

Q. Do you agree with it?

A. I think, yes, sir; because it aligns with what I said before. In the end, the owner of the product is the custodian of the product. That's what this says.

Q. Go to Page 3, please. While I've got this, I

may as well ask you everything I need to about it.

A. Yes, sir.

Q. There is a caption called "Pre Filing Investigation." Do you see that?

A. Yeah.

Q. And it says, "When a client comes to you suspecting that he or she has taken an adulterated drug, you should tell the client to save the drug, the container, and all labeling and packaging information."

Do you see that?

A. Yes, sir.

Q. The next sentence says, "A laboratory must analyze the drug to test for its active pharmaceutical ingredient and for strength and purity."

Do you see that?

A. Yes.

MR. MILLER: Object to form.

Q. Do you agree with it?

A. Well, actually, I agree with him. It's what I had said it before, Matt.

Q. Okay. Go to Page 4. At the very bottom it should say, "Training records" in bold.

A. Okay.

Q. Have you looked at any training records in

this case?

A. No, sir.

Q. Go to Page 5, please. The second bolded section is called "Standard Operating Procedures."

A. Yes, sir.

Q. Have you looked at any SOPs of Actavis or Amide?

A. Yes, sir.

Q. How many of them?

A. I looked at -- my guess would be three or four around the specifics that I was looking at, compression.

Q. Do you know, either by number or topic, what those SOPs were?

A. One was compression, using the Stokes machine, and the other was the blending of powders. I don't remember the numbers.

Q. Okay.

A. I'm sorry.

Q. All right. I don't have any questions about that. You can put that back on the stack.

A. Is this -- what is this? I'm sorry.

Q. All right. I want to ask you some questions about manufacturing processes for solid oral dose --

A. Yes.

Q. -- pharmaceutical products; okay?

In the ANDA and in the batch records, is the formula for the product there?

A. Yes, sir.

Q. And the formula has the ingredient and the amount of the ingredient that is supposed to go in; correct?

A. Yes, sir. It has the dosage form amount as well as the amount that goes into the batch to make the product, yes, sir.

Q. And presumably those ingredients need to be mixed in the appropriate proportions in order to comply with the formula. Is that right?

A. That's correct.

Q. And typically when the actual mixing is done, one person mixes it and a second person verifies by watching that that is done appropriately. Is that right?

A. Customarily, yes, in all cGMP environments, one guy does, one guy verifies.

Q. All right. And if we were going to do an investigation of tablets that were normal in size, but somehow out of their finished product specifications and just, for example, let's say on the high side, one place you might look is whether the batch was mixed

appropriately from the start; correct?

A. Yes, sir, that's the standard review, batch record review.

Q. You would want to know whether they put too much active pharmaceutical ingredient into that batch or other batches; right?

A. Right. We check by the weight sheets.

Q. Have you seen any FDA citations or warnings in any FDA 483 or warning letter to the effect that Actavis improperly mixed Digitek?

A. No, sir. Everything that I've reviewed suggests that the process was done according to the way it's written.

Q. Once the ingredients are mixed, do they weigh it?

A. There are steps that they confirm that the material has been put in and removed. That's customary when you do a process transfer from a blender to a drum to a blender. Yes, sir, they do do that.

Q. Okay. Why do they do that?

A. That's to confirm that they haven't had any untoward losses during the manufacturing, okay? A drop on their shoes.

Q. I guess theoretically you don't want any

untoward gains either. Is that right?
A. Right. Gains is much worse than loss, correct.
Q. And this sort of weighing --
A. Yes.
Q. -- at each stage of the process is sort of a quality check to see whether you have untoward gain or loss; right?
A. Absolutely.
Q. And also, if you have validated the process, it gives you a benchmark so you know whether you're meeting targets from your validated processes; correct?
A. Correct.
Q. Do you know what yield calculations are?
A. Yes, sir.
Q. Are you familiar with doing that yourself --
A. Yes.
Q. -- at Novartis?
A. Yes, sir.
Q. In any of the batch records you reviewed, did you see any inappropriate yield calculations?
A. Absolutely not, sir; they were done correctly.
Q. Did you see -- I'm sorry.

Did you see any FDA warnings or 483 citations to the effect that the yield calculations were somehow trending inappropriately?

A. That I did not see, sir.

Q. Let's talk about blenders.

A. Okay.

Q. Tell me about your actual experience in operating blenders or conducting blend uniformity sampling.

A. I established the SUPAC equipment guidance of similarity for FDA, the formal industry guides; so my -- my understanding of the blending aspect was key in that case. Our objective was to determine like versus like.

As far as blend uniformity, it's expected in all products prior to launch. And I've done 21 NDAs.

Q. Okay.

A. Okay. You asked for background. Sorry.

Q. At Page 10 of your report --

A. Yeah.

Q. -- you are talking about how at Actavis the final step blender is of a different geometry?

A. Correct.

Q. Do you see that?

A. Yes, sir.

Q. Okay. Was this change of geometry -- I'm sorry.

MR. MORIARTY: Let me withdraw that question.

Q. Was the blender configuration in the ANDA --

A. Absolutely, sir.

Q. -- approved by the FDA?

A. Yes, sir, it was in there.

Q. It's in all the batch records?

A. Yes, sir.

Q. Has FDA ever made a citation or warning or criticism of Actavis or Amide for its blender configuration with Digitek?

A. No, sir. This is simply my opinion.

Q. Now, you referred at various points in your report to a book called "Pharmaceutical Process Scale-Up."

A. Uh-huh.

Q. Did you not?

A. Yeah.

Q. You brought it with you?

A. I didn't know if you would have a copy.

Q. I just happen to.

What edition do you have?

A. It was only the one, Matt, but let me check.

Q. That's okay. That's fine. I don't see an

edition on mine either.

A. It wasn't exactly a best seller.

I've got a copyright of 2002. Okay?

Q. Okay. So at least two of us have looked at this book?

A. Yes, sir.

Q. And the focus of this book, if you go to the preface, the first sentence of the book says, "Pharmaceutical process scale-up deals with a subject both fascinating and vitally important for the pharmaceutical industry, the process of transferring the results of R&D obtained on the laboratory scale to the pilot plant and finally to production scale."

Did I read that right?

A. You did.

Q. And essentially that's what this whole book is about; right?

A. That's what it's supposed to be about, yeah.

Q. And if you go to the next page, in the Introduction to the book, it says, "Scale-up is generally defined as the process of increasing the batch size." Do you see that?

A. Uh-huh, yeah.

Q. Do you agree?

A. Yeah. Because that's when you talk about

scale-up, right.

Q. Okay.

A. Since this book has been published, just as a point, you refer to scale-up. People prefer to just scale-out. In other words, they don't change the scale any more, Matt. They try to just make more of it.

(A discussion is held off the record.)

A. They don't scale up. They scale out.

I'm sorry, Matt, that's that that PhD. ...

Q. What does "scale out" mean?

A. "Scale out" means if you were making it -- say you were making 50 kilograms in a process. Independent of what the process is. Rather than take that and try to make 500 kilograms, you make multiple 50 kilogram processes.

So rather than take the risk of the scale, you remain small and you leverage your knowledge without taking the risk of scale-up.

Q. Okay.

A. I'm sorry.

Q. Go to Appendix C of the book, Page 415.

And while you are looking for that, this is "Pharmaceutical Process Scale-up" edited by Levin, L-e-v-i-n. Is that right?

A. Uh-huh.
Q. Go to 415, Appendix C.
A. Yeah.
Q. Is this called "Guidance For Industry, SUPAC," dash, "IR/MR, Immediate Release and Modified Release, Solid Oral Dosage Forms, Manufacturing Equipment Addendum"?
A. That's right.
Q. I would like you to go to Page 422.
A. Uh-huh.
Q. Do you know what kind of blenders Actavis used --
A. Yes, sir.
Q. -- for blending Digitek?
A. Yes, sir. A V blender and a double cone blender.
Q. Well, they were made by Paterson Kelly; correct?
A. That's correct.
Q. And if you look at Page 422 --
A. Right.
Q. -- Table 3 under diffusion blenders --
A. Right.
Q. -- both V and double cone, Paterson Kelly, are listed there; right?

A. That's right. That's how we did that.
Q. And while I got this book out, go to Page 435.
A. Uh-huh.
Q. Which is Table 6?
A. Okay. We got it.
Q. This is tablet presses; right?
A. Right.
Q. Gravity feed tablet presses, Stokes is on the list; right?
A. Yes, sir; yes, sir. It's right here. I wasn't -- I'm sorry.
Q. So at Page 10 of your report, you specifically refer to Pages 115 to 132, which is Chapter 5, called "Batch Size Increase in Dry Blending and Mixing." Do you see that?
A. That's right.
Q. And this is about scale-up, so you are going from one batch size to a bigger batch size.
Is that right?
A. That's right.
Q. And this whole chapter's about blender configuration in that situation; right?
A. Correct.
Q. Now, when Digitek was being manufactured in

2004, '5, '6, '7 or '8, they didn't change the size of the batches; did they?

A. They did scale it up from their bio pilot logs, yes, sir.

Q. Well, not in 2004, '5, '6, '7 or '8; correct?

A. Oh, I'm sorry. Yes, sir. No, sir.

Q. And the process for the manufacture of Digitek in those years was a validated process; was it not?

A. Based on the three batches, yes, sir.

Q. Okay. So is there anything in this chapter of the book to which you refer that says that the Paterson Kelly blending configuration used for Digitek was somehow against an industry standard or inappropriate?

A. When we put the SUPAC guidance on --

Q. Wait. Yes or no.

A. Sorry.

Q. Start with yes or no?

A. May I have the question again, please? Sorry.

Q. Is there anything in this chapter of the book to which you refer that says that something like the Paterson Kelly blender configuration used for Digitek was inappropriate or against an industry standard?

A. Yes.
Q. Show me where in this chapter it says that?
A. Page 119, bottom.
Q. Exactly where?
A. "Common violations," the last paragraph, Matt. Right here.
Q. I'll get there. Okay.
"Common violations of this approach can immediately cause problems, include (sic) the attempt to scale from one geometry to another." Did I read that right?
A. That's correct.
Q. And if I understand scaling in the context of this book, you are talking about going from one batch size to another; right?
A. That's correct.
Q. Which didn't happen in 2004 through '8; correct?
A. I think -- that's correct. I think my comment is in retrospect.
Q. And the FDA, I believe I may have asked you this before, never had any problems with the blender configuration?
A. No, sir, they did not.
Q. In this paragraph in your report at Page 10,

when you are talking about these blenders, you don't use the word "negligent;" do you?

A. Absolutely not.

Q. You don't use the words "against industry standards:" Do you?

MR. MILLER: Object to form.

A. Can I read it? I don't recall using those words, but let me double-check.

I do not see that word here.

Q. Let's go to the next paragraph of Page 10.

A. The evaluation?

Q. "The evaluation of blend uniformity is a difficult task."

What does that mean?

A. "Difficult task" means that it requires a -- again, what I had indicated, a very rigidly established plan that has to be followed: How the product is going to be withdrawn, how big the product is going to be, how the samples have to be handled and recovered.

Q. I want to know what you mean by "difficult task"?

A. Because there are so many different things that can contribute to a false positive or a negative -- or a positive false input.

Q. Do many companies struggle with blend uniformity?

A. I can't speak for all the companies I've worked for; however, I can tell you that many of the products I worked on, it was a struggle, yes, sir.

Q. All right. And actually -- companies actually don't have that much problem with blend uniformity? Companies have problems with blend uniformity sampling; right?

MR. MILLER: Object to form.

A. Good point, Matt. The point is -- the key is: If you have two wristwatches, what time is it? So is your sample defective or is your blend defective? That's where the difficulty in task comes in: Illucidating which is wrong and which is right.

Q. All right. Now, I can't remember whose principle or law this is; but when you test blend, you change the nature of the blend in the process of testing; do you not?

A. That comes back to sample handling. Okay? In the correct world, if you are trying -- your point is in a static bed, when you pull the sample, you have disrupted the bed; therefore, the bed is different.

Q. Okay.

A. Right?

Q. So am I correct that various pharmaceutical companies have tried to obtain exemption from blend uniformity sampling because it is such a variable and difficult problem?

A. That is correct.

Q. Are there industry groups in the pharmaceutical companies that have petitioned the FDA to do away with blend uniformity sampling because of its difficulty?

A. There has been a great deal of information transmitted on that point, yes. And I can point to that FDA does give some latitude on high-dose composition.

Q. Now, did FDA ever say in a 483 or warning letter that the process by which we test blend uniformity was inappropriate?

I asked you earlier about the sampling plan itself, where and how many, and you said no. Now I'm asking you about anything else about the actual test process.

A. Matt, I'm just looking here to make sure.

MR. MILLER: Take your time.

A. I've looked at these things. Let me just look at one more thing, Matt.

I dot not recall FDA having a problem with

the way they tested their samples.

Q. Okay. Did you review the SOP for blend uniformity sample? Actavis' blend uniformity sampling SOP for Digitek?

A. I've read all of the procedures. I don't recall if I actually read that SOP, to be perfectly honest.

Q. Now, you are aware that there is an FDA 483 about some blend uniformity investigations. Is that right?

A. Due to out-of-specifications observations, yes, I am.

Q. Now, how many batches were affected? How many batches were involved in that 483 citation?

MS. CARTER: Object to form.

A. I don't recall.

MR. MORIARTY: Did you just object?

MS. CARTER: I did.

A. I don't recall, Matt.

Q. Do you know what -- Well, you can look at the 483. My memory is it's three batches.

A. Okay. Let me look.

Q. I believe it's the May, 2008 483.

Am I wrong about that? I thought it was Observation 3, but --

MR. MILLER: Maybe it's 4.
Q. Do you see it there?
A. Okay. Three batches, Matt. Thank you, yes.
Q. So if we go by the number of recall batches, that's three out-of-spec --
Let me start from scratch.
Those three investigations had to do with an out-of-spec result in one out of ten samples for each batch; correct?
MR. MILLER: Object to form.
A. As I recall, yeah. That was -- it was the same location every time.
Q. Okay.
A. Right.
Q. And on retesting, they didn't confirm the out-of-spec result; correct?
A. They ran the replicate samples and did not see the failing result, correct.
Q. When you say "replicate samples," at the time you sample a dry blend like this, you take two or three samples from each site; correct?
A. Absolutely.
Q. So if it calls for ten sites, you are taking 20 or 30 samples?
A. Customarily 30, yes.

Q. So if the first sample at the right top fails, there are backup samples taken at the same time that you can test; correct?

A. That's correct.

Q. Is it your memory that in each of those three instances, a backup sample passed?

MR. MILLER: Object to form.

A. As I recall, yes. As I recall, they passed. Because I don't think they had to go much beyond two in one case, yeah.

Q. If you read the -- Well, did you read the actual Actavis investigations of those blend uniformity --

A. Of these particular batches?

Q. Yes, sir.

A. Honestly, I can't say that I read the ones specific to these batch numbers; no, sir.

Q. All right. Are you aware that in general with those three batches, they increased the sample size for the finished product testing?

A. To 30 tablets, yeah. That I am aware of.

Q. And all three of those batches actually passed finished product testing; correct?

A. Yes, as I recall.

Q. All right. Now, do you know how many of

those three batches were actually released and sent to the market?

A. No, sir, I don't recall that.

Q. And in that 483, isn't the FDA's real focus of their observation that Actavis did not, in addition to the QC investigation, conduct a manufacturing investigation?

MS. CARTER: Object to form.

A. Matt, I'm just reading it again. May I please have the question again?

Q. Yes, sir. Are you ready for the question again?

A. Yes, I'm going to pay attention this time.

MR. MORIARTY: Mark, can you read that one back, please?

A. Sorry.

(The question is read.)

A. Yes.

Q. So let's go back to Page 10 of your report, the second -- well, actually it's the last paragraph.

A. Uh-huh. The reliability.

Q. Your second sentence starts with the word "Repetitive failures at the same blender location."

A. Uh-huh.

Q. Do you have any other instances of

out-of-spec results besides the three we just talked about?

A. Let me just check one location.

For clarity to answer your question, by "repetitive," I think it's the same location failed repeated -- but not repetitively. I think I misstated it. It's the same location failed in several of these batches.

Q. Well, my question is: Do you know of any other batches --

A. Other than these three, no.

MR. MILLER: You have to wait.

Q. And the three that the FDA is referring to are 70148A; right?

A. Uh-huh.

Q. That's a yes?

A. Yes, sir.

Q. 70207A?

A. 7070A (sic), yes, sir. And 70207A, yes, sir.

Q. So in the last paragraph of Page 10 of your report, when you talk about the firm "struggling with the procedure and repetitive failures," these are the only three of which you are aware; correct?

A. Those are the three that I'm aware; in addition to my own experience in how difficult this

task can be.

Q. And the last part of your statement says, "Blend sampling program was ineffective and not predictive of final product quality."

What's the basis for that statement?

A. My basis for that statement is: If you cannot isolate that the blend itself is uniform or non-uniform, this gets back to: Is the sample reliable or not, you cannot assume that the blend is indicative of anything downstream. It gets back to the continuum of the whole structure.

It really gets back to the heart of my first comment, the comment we had about the blend.

On -- in balance, this stuff is -- everything seems right. But if you start to pull things out of context and ask the questions in an investigation, it starts to bring to light a systematic problem that, again, is inferential at best at this stage, Matt, if you know --

Q. But you have to pull it out of context to do that; right?

A. And, again, someone skilled in the art like myself would do that.

Q. So I want to jump ahead just for a moment.

A. Go ahead.

Q. You have looked at all the annual reports which nicely condense and summarize the finished product test data for this product; correct?
A. No, I did not.
Q. You haven't looked at the annual reports?
A. No, sir.
Q. Do you know whether any batch of Digitek, just among the recalled batches, failed finished product testing?
A. I believe one did, sir.
Q. Which one?
A. That I'd have to check.
Q. Just so we are clear. Do you know of a single batch of Digitek that was submitted to the QC testing for its USP testing that failed those tests?
MR. MILLER: Object to form.
Q. And if you know of one, tell me what batch number it was?
A. I can't tell you what batch number it is. I only have a picture of a rejected form. I'd have to go back and dig it out. I know it's not in this pile.
Q. Okay. Well, do you know of any batch that was actually sent to market that failed finished product testing at Actavis?
A. If all -- if all of the parts and pieces are

working together, that should never happen, sir. Right?

Q. Well, you know that each batch is tested; correct?

A. Right, right.

Q. And that there is actual data available; correct?

A. Uh-huh.

Q. So have you looked at the data to see whether any batches failed finished product testing?

A. In the batches I looked at, no. Only the batches I looked at.

Q. Well, let's just start with the recall. Out of the 152 batches that were actually sent through Mylan to pharmacies, did any of them fail final product testing?

A. Not to my knowledge, sir.

Q. And if we tried to do the math, and I haven't done it before today, if we just take the 152 recalled batches, and say that there were 30 blend uniformity -- I'm sorry.

MR. MORIARTY: Let me withdraw that question.

Q. We just take the recalled batches and say that there was one blend uniformity battery for the whole batch, that would be ten samples per batch;

correct?

A. Thirty.

Q. Well, let's just take one set of them, not three deep. You are talking about 1,520 blend samples; correct?

A. For those batches.

Q. Yes. Right?

A. Right, 152 times ten.

Q. And there were three that were out of spec; right?

A. Uh-huh.

Q. That's a yes?

A. Yes, sir.

Q. Each of the three that were out of spec weren't confirmed on retesting; correct?

A. That's correct.

Q. And you think even if those batches were included in the recall set, which we are not sure they are, three out of 1,520 constitutes repeated failures that are predicted -- mean that blend uniformity aren't predictive of final product quality?

A. Absolutely. The reason is because of the uncertainty in doing the sampling.

Q. All right. Did FDA ever actually say that any Actavis batches of Digitek failed blend uniformity

testing?

A. They called it out of specification. They didn't say it failed.

Q. Okay. Did they ever say that any batches of Digitek failed blend uniformity testing?

A. Not that I recall, other than what's here.

Q. If somebody just colloquially -- colloquially said that those three were blend uniformity failures, that wouldn't technically be correct; would it?

MR. MILLER: Object to form.

A. I want to make sure I -- may I have the question again, please?

Q. If somebody colloquially --

A. Okay.

Q. -- said those three are blend uniformity failures, that would not be technically correct?

MR. MILLER: Object to form.

Q. Am I right?

A. If you do the repeat test and they pass, no.

To be clear, there is FDA guidance on doing just that.

Q. We have only got a couple of minutes left on the tape, so we might as well take our break now.

THE VIDEOGRAPHER: Please stand by.

MR. MORIARTY: And we're off the record?

THE VIDEOGRAPHER: We are going off the record. The time is 11:02 a.m. This is the end of Tape Number 2.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 11:12 a.m. This is the beginning of Tape Number 3.

Q. Now, Dr. Somma, I touched very briefly earlier on the concept of batch yields; correct?

A. Yes, sir.

Q. And would you agree with me that if you consistently put too much active pharmaceutical ingredient into your solid oral dose, it could be detected at a number of different places; and one might be the inventory of your active pharmaceutical ingredient; correct?

A. Absolutely.

Q. Another could be at the blend uniformity stage. Is that correct?

A. That is correct, assuming the sampling and the testing is good, sure, yeah.

Q. Another could be your finished product stage?

A. Absolutely. And at that stage it becomes

compounded by the blend part and the compression part.

Q. Okay.

A. You can still find it. I agree with you.

Q. Sure. And if there was testing done by an outside entity for whatever reason, it could theoretically be picked up there; correct?

A. Theoretically, yes.

Q. All right. And if you were consistently putting too much adverse -- I mean active pharmaceutical ingredient into your product and it had the potential to harm patients, another potential place to see a problem would be an increase in your adverse event reporting. Is that true?

A. I would -- I would agree with that, yes.

Q. Okay.

A. It's a true statement.

Q. Now, I think you told me earlier you are not an expert in pharmacovigilance; right?

A. No, sir.

Q. Have you done any study in this case of Actavis' pharmacovigilance or their adverse effect reporting rates?

A. No, sir.

Q. And a pharmacovigilance expert for the plaintiffs, a Dr. Frank, was deposed yesterday, and I

know you don't know anything about what she said, but would you generally defer to an expert like her in pharmacovigilance on the subject -- on that subject in this case?

MR. MILLER: Object to form.

A. Absolutely, Matt.

Q. Okay. And to stick with this batch yield concept, if a company consistently made double thick tablets, there would be a number of places you might catch that as well; correct?

MR. MILLER: Object to form.

A. You would expect to catch that at certain places. I would have to agree with that.

Q. For example, even if we just worked backwards, if you used the appropriate amount of ingredients from the start but made double-thick tablets, you wouldn't have as many tablets; right?

A. If you made all of them double thick. Yeah.

Q. Right.

A. Occasionally one, Matt; really, realistically, you couldn't detect it.

Q. I understand that. But I'm saying if you made lots of them, you wouldn't have as many tablets; right?

A. You're correct.

Q. Okay.
A. You're correct.
Q. Hence, you wouldn't have as many bottles; right? To fill at the packaging station?
A. You're correct, yeah.
Q. And those sort of things are looked at by companies as further quality checks to see if the processes are following their validated methods; right?
A. Absolutely correct, Matt. The problem would have to be pretty extreme, though, to pick it up in that manner.
Q. Okay. Well, it sounded to me like your pharmaceutical consulting engagement where they had extra-thick tablets was an instance where there were just a few among either a batch or several batches; correct?
A. That's right.
Q. Was it one batch?
A. I looked at the batch that the sample was returned from.
Q. Did they only find them in one batch?
A. I don't know what -- to be perfectly honest, I don't know what else they found. I did not find any indication of them in the batches, before and after, I

looked at; no, sir. There were no complaints, no returns, no nothing.

Q. Okay. And theoretically in order to actually harm patients, for enough of these to get out into a lot of bottles and out through the entire distribution system over years and years, you would have to make a lot of extra-thick tablets; wouldn't you?

MR. MILLER: Object to form.

A. I guess, but it only takes one bad tablet to create a harm, and that's why this complaint was dealt with like this particular company that I worked for, yeah.

Q. Well, I think we established that you are not a pharmacokineticist, a pharmacologist; you are certainly not a physician; correct?

A. Definitely not.

Q. You don't know whether one Digitek tablet that was extra thick would harm a patient or not; do you?

A. No, sir. And the fact is that we don't even know what the composition of that thick tablet was.

Q. There could be an extra-thick tablet that's just bigger because it wasn't compacted appropriately; right?

A. So that would be -- that is certainly within

the realm of possibility, yes, sir.

Q. All right. So if you subjected that tablet to a hardness testing, it might shatter like an egg; correct?

A. If it would survive packaging, yes, sir. Which is what friability and hardness is supposed to prevent, right.

Q. Do you know how many people in the United States were described digoxin between 2006 and 2008?

A. No, sir.

Q. Do you know how many prescriptions were written for digoxin between 2006 and 2008?

A. No.

Q. Do you know how many people were taking Digitek between 2006 and 2008?

A. No, sir.

Q. Do you know how many prescriptions were written for Digitek between 2006 and 2008?

A. No, sir.

Q. Now, do you know the theoretical batch size of a Digitek 125 microgram batch?

A. 4.8 million.

Q. And the theoretical size for a 250 microgram is what?

A. I think it was 4.2 million, but that's by

memory.

Q. Okay.

A. I don't know if that's correct.

Q. So if you do the math of 152 recalled batches, you're up in the 688.2 million range for tablets; are you not?

A. Yes.

Q. Depending on how many batches of each?

A. How many tablets are made; yes, sir.

Q. All right.

A. It's 152 times 4.8, right, okay.

Q. Do you know how many were recalled in either of the two dose strengths?

A. No, sir.

Q. Of the number of batches that were actually recalled from the market, do you know how many of those tablets never made it to consumers?

A. No, sir.

MR. MILLER: Object to form.

A. No, sir.

Q. You know that there was a recall; correct?

A. From what you told me, 152 batches; yes, sir.

Q. Well -- and tablets were supposed to be sent from pharmacies and hospitals that still had them back to a recall center; correct?

A. Right, I was aware of that, yes, sir.
Q. Do you know how many tablets were returned?
A. No, sir.
Q. So I want you to assume that -- and I just keep referring to the recall batches more for convenience, but if you want to go back to 2004, we can.
Do you know whether each batch of Digitek that was made between 2004 and 2008 was subjected to quality control, USP method, finished product testing?
MR. MILLER: Object to form.
A. Based on what I've seen, every batch was tested, yes, sir.
Q. Right. And you don't know of any that failed that testing; do you?
A. To my knowledge, no, sir.
Q. And you don't have any question or criticism of the sample size or the method they used; correct?
A. No, sir.
Q. Or the integrity of the data?
A. No, sir.
Q. So what I want to ask you is about testing that was done by other people.
A. Okay.
Q. Do you know what the batch certification

program was?

A. That they -- as I recall, based on what I've read, it was samples had to be provided to FDA for them to confirm at their laboratory that these met requirements.

Q. Right. Was that going on when you worked at Novartis in the '90s?

A. I wouldn't know that, sir. I wouldn't.

Q. All right. I want to hand you what actually should be in the stack, Exhibit 4?

A. It was right on the top, yes.

Q. It should be near the top. I had them in order.

A. It was right here. I remember looking at it.

Q. Okay. Do you have Exhibit 4?

A. That's it.

Q. That's a letter to Amide at the time from FDA, is it not?

A. Yes, sir.

Q. Certifying nine batches of Digitek; correct?

A. Uh-huh, yes, sir.

Q. Presumably all tested by FDA itself. Is that right?

A. That's how I understand that, yes. And they all met requirements.

Q. And Exhibit 5 is in that stack?
A. Yes, it is.
Q. Is that a July, 1995 letter from FDA to Amide exempting them from the batch certification process?
A. Yes, it is.
Q. Presumably at that point FDA was confident that Amide was making the product within its specifications consistently; correct?
MR. MILLER: Object to form.
A. As far as I read this, yes. Everything was as they anticipated it would be.
Q. Do you know what Quantic Regulatory Services is?
A. It's a consulting firm as far as I know, sir.
Q. Do you know anything about them?
A. Other than that their specialty is consent decree remediation. That's the only thing I know about them.
Q. Do you know if they are reliable?
A. I couldn't say that one way or the other, sir.
Q. Are they well-regarded by FDA?
MR. MILLER: Object to form.
A. I think that they are on the list of people that FDA says to use in consent decree remediation. I

would think that says it right there.

Q. Okay. And I'd like you to look in the exhibit stack for Exhibit 22 and 23. Do you have 22 and 23?

A. Yes, I do, Matt.

Q. All right. I'm going to have to do this from memory because I can't find my copies of those two exhibits, but 22 should be a warning letter from the FDA. Is that right?

A. That's what it says, yes, sir.

Q. And -- oh, I found it.

At the back, second-to-last page, last paragraph. They say, "We feel that to provide such assurance, your firm should promptly initiate an audit program by a third party having appropriate cGMP experience to provide assurance that all marketed lots of drug products that remain within expiration have their appropriate identity, strength, quality and purity."

Did I read that correctly?

A. Yes, you did.

Q. This is an invitation by the FDA in a warning letter to hire a consultant; correct?

MR. MILLER: Object to form.

A. As I understand it, yes, sir.

MR. MORIARTY: All right. What's wrong with the form of that question?

MR. MILLER: I object to the term "invitation."

MR. MORIARTY: Okay.

Q. Let's get back to the basic definition of a warning letter. A warning letter is not a "you must" in the eyes of the FDA; correct?

A. Yes, Matt. I recall we discussed it and it was informal.

Q. Right. And it is urging voluntary compliance with the regs; is it not?

A. Yes, sir. It's -- you don't ignore them, Matt. Let's put it that way.

Q. I understand from a company perspective you wouldn't want to ignore them, but --

A. Gun to your head?

Q. "Invitation" isn't an inappropriate word when -- in your mind, when I asked you that question; is it?

A. To be honest, I was thinking what -- what they were asking here/ and to me, yeah, well, that means you better get yourself a consultant, period, end of story.

Q. Okay.

A. You know.
Q. All right.
A. What you call it, whatever.
Q. All right. Let's go to Exhibit 23.
Have you ever seen Exhibit 23 before?
A. No, sir.
Q. All right. Exhibit 23, do you know --
MR. MORIARTY: Let me withdraw and start over.
Q. Do you know that in response to Exhibit 22, Actavis went out and hired Quantic Regulatory Services to do the remediation of that warning letter?
A. I did not know that as fact.
Q. Okay. Well, I want you to assume that my client hired Quantic, and that Quantic looked at batch -- batch records. Okay?
Now, if you look, if you flip through here you will see that obviously pages are redacted with the names of other products, but at Bates Page 1867202, 1867202, you see that there are Digitek batches there?
A. Yes, sir.
Q. And then if you flip further back to Bates Page 1867214, and spilling over onto the next page, there are a number of other Digitek batches; correct?
A. Yes, sir.

Q. Do you know what kind of batch record review they performed?
A. No, sir.
Q. You don't know anything about the protocol they used to analyze the batch records?
A. No, Matt, I don't know.
Q. All right. Do you know how many of these batches wound up being in the recall --
A. No, sir.
Q. -- batches?
A. No, sir.
Q. Let's go back to the cover page.
A. This?
Q. Yes. It says, "On December 21st, 2007, Quantic provided Actavis with a statement indicating the audit was complete and the manufacturing and laboratory records have reliably confirmed the identity, strength, quality and purity of the marketed products."
Do you see that statement?
A. Yes, sir.
Q. If that is in fact was Quantic concluded, do you have any reason to disagree with them?
A. No, sir, I don't, based on what I know and what I've read.

Q. Do you know whether or not FDA accepted Quantic's analysis and this letter from my client in remediation of the warning letter, or whether they rejected it?

MR. MILLER: Object to form.

A. No, sir.

Q. Okay. I'm going to go through a number of exhibits in this stack, so --

A. Okay.

Q. Let's go to Exhibit 24. Do you have 24?

A. Yes, Matt, I do.

Q. Have you ever seen it before?

A. No, sir.

Q. I'm sorry?

A. No, sir.

Q. You didn't see it yesterday when you met with Pete and Meghan?

A. No, sir.

Q. Do you know what a 484 sample is?

A. Yes, sir. It's a sample collection, sir.

Q. Did FDA ever come to Novartis and collect 484 samples of drug products?

A. Yes, sir, but I was not involved. I just knew of it, sir.

Q. So if you go to the first page of Exhibit 24,

and you and I might have to get a lot closer because I can run you through these quickly.

But if you look here --

A. Okay.

Q. -- this is Sample 377410.

A. Yes, sir.

Q. Do you see that?

A. Yes, sir.

Q. Down to the left, it was collected February 9th of 2007. Do you see that?

A. Oh, yeah, great. Right here. February 26.

Q. I'm pointing to these over here if you want some guidance. I've highlighted them.

A. I'm sorry. Okay. Yeah. February 9th, right.

Q. And in the middle where I'm pointing with my pinky, it has the manufacturer's batch number as 70078A1. Do you see that?

A. Yes, sir.

Q. Down here it describes the sample, 200 count bottles of digoxin, .125. Is that correct?

A. Right.

Q. And if you want to flip through all this you can, but I will represent to you that they subjected this to USP method, assay, content uniformity --

A. Right.
Q. -- testing, and all the backup data from the chromatographs is attached to this. Okay?
Do you have any reason to disagree with any of what I just said?
A. Absolutely not. Just for clarity, Matt, these are -- this was done by the FDA laboratory or somebody; correct?
Q. They tested it; right?
A. Yeah, fine.
Q. To your knowledge, FDA does have labs that do this; correct?
A. Yes, sir, they do, forensic laboratories.
Q. And if you go to this page, if you can see this page, in the upper right-hand corner where it says, "District or lab," it says, "DEN/DO."
They have a lab in Denver; don't they?
A. Uh-huh.
Q. Yes?
A. Yes.
Q. I'm sorry to say that, but Mark needs to hear it.
A. I understand, sir. It's a bad habit of mine.
(A discussion is held off the record.)

Q. And to your knowledge, did this sample pass all of the tests to which the FDA subjected it?

MR. MILLER: Object to form.

A. Well, I haven't read through, but my -- based on what's here, meets, yes.

Q. All right.

A. There is no reason to think that it doesn't.

Q. Let's go to Exhibit --

Well, do you have any -- have you seen any evidence to indicate that this batch did not meet all of its specifications?

A. Absolutely not.

Q. Let's go to Exhibit 25. Is this another 484 sample report?

A. It's similar format of sample collection, yes.

Q. Up here it says Sample 44881; does it not?

A. Yes, sir.

Q. And down here if you flip through this, you can see that they collected -- if you go to the second page, on December 3rd, 2007 they collected from a Wal-Mart Pharmacy warehouse 200 count bottles of Digitek; right?

A. Uh-huh, yes, sir.

Q. Batch 70298A1; right?

A. 70298A1, yes, sir.
Q. And on the first page, if you flip back, they have a Lab Conclusion near the bottom. It says, "The product meets specifications for identification, dissolution and content uniformity." Is that right?
A. Yes, it does say that.
Q. Now, have you seen any evidence in any documents that you've reviewed that shows that any of the tablets from this batch were out of specification?
A. No, sir. But where does it say the product meets specifications on this one? Did I miss that? I'm sorry. I don't --
Q. Are you talking about Exhibit 24?
A. I'm sorry. 24, yeah.
Q. Do you want to dig through it?
A. Well, I just -- it's not a headline like this one is. I can see that.
Q. If you want to review it, go ahead. If you find that that batch when tested by FDA was out of specs --
A. No.
Q. -- let me know.
A. I'm agreeing it's in spec. I'm just wondering how come they don't put it in the front on this one. Go ahead.

Q. Let's go to Exhibit 26. Look at the second page of that one. I don't know why it got marked that way.

A. Yes, Matt.

Q. Do you have it?

A. Yes, sir.

Q. It's Sample Number -- the shading is so bad. Oh, Sample 448892.

A. Yes, sir. And that meets requirements.

Q. And it was collected in December of 2007 from a Wal-Mart Pharmacy?

A. Yes it was.

Q. And it's Batch 70664A. Is that right?

A. Yes, it is.

Q. And on the first page of Exhibit 26, "The product meets specifications for identification, dissolution and content uniformity."

Do you see that?

A. Yes, sir.

Q. Have you seen any evidence the tablets from this batch were out of specification?

A. Not in anything I reviewed.

Q. Let's go to Exhibit 27.

A. Okay.

Q. Before I ask you about Exhibit 27, when you

worked for Novartis, were you ever made aware after the fact that FDA had done a 484 sample and passed your company's products?

A. Not customarily, Matt, no.

Q. Okay. As a consultant when you are doing an investigation about the integrity of the product in the field --

A. Yeah.

Q. -- would you inquire about 484 samples that may have been tested by FDA itself?

A. In -- when we would interview the client, just to get a sense of what the level of involvement was, yes, sir.

Q. Okay. Is it interesting and helpful information to know?

A. It's another set of eyes looking at the information in an independent laboratory; always good to have as a backup validation, Matt.

Q. It's -- is it more than a set of eyes? It's -- it's scientific testing of tablets; right?

A. It's scientific testing of tablets. I apologize for denigrating it to "eyes," but that's what I mean; it's another set of expertise looking at it. Independent, if it's regulatory or somebody else.

Q. Okay. And FDA, when they take the samples,

can take as many as they want; correct?
A. That I don't know, sir.
Q. Can they test as many as they want?
A. Again, I'm ignorant of that fact. I don't know.
Q. Do you assume that FDA chooses a sample size that they think is statistically significant?
A. Based on uniform --
MR. MILLER: Object to form.
A. I guess that's a reasonable estimate based on batch size. I would also think that FDA could take whatever they want.
Q. Okay. So let's go to Exhibit 27.
A. Okay.
Q. This is FDA Sample 453913; correct?
A. 453913?
Q. Yes?
A. Yes, sir, it is.
Q. Okay. Collected February 15, 2008; right?
It's up here in the left-hand corner.
A. Sorry. Yes, sir.
Q. Batch 70737A; correct?
A. Yes, sir, yes, sir.
Q. And it was collected from a warehouse -- I'm not sure where. But if you go to the third page,

there's a Lab Conclusion; right?

A. Yes.

Q. Did it pass all the tests to which FDA subjected it?

A. It says that it meets USP requirements for identification, CU and dissolution; yes, sir.

Q. Let's go to Exhibit 28.

Now, I know before today you hadn't seen these exhibits, but did you know generally that FDA had repeatedly tested Digitek in the field?

A. No, sir.

Q. Do you think for your analysis in this case, it would have been important for you to know that?

A. No, sir.

Q. You don't think statistically significant testing by FDA itself corroborating my client's QC results is significant information?

MR. MILLER: Object to form.

A. I would say based on balance, if a firm comes to me and offers a batch record which they say is approved, I don't need any outside corroboration. To answer your question specifically, that would have been nice, but I take it at face value what the client has done.

Q. All right. So Exhibit 28 is FDA Sample

454866; is it not?

A. 454866, yes.

Q. And it's another sample of a Digitek batch; correct?

A. Yes, sir.

Q. And if you look way at the back, the third from the last page, you will see it was collected February 15th, 2008. Upper left corner.

A. Okay, yes, sir.

Q. And it's Batch 70811A; correct?

A. Yes, sir.

Q. It was collected from a McKesson warehouse. Is that right?

A. In Duluth, yes, sir.

Q. And let's go all the way to the front.

Is there a Lab Conclusion? First page.

A. Same as before, Matt: Meets requirements for dissolution and content uniformity.

Q. Let's go to Exhibit 29, please. Do you have it?

A. Yes, sir.

Q. Do you see that it is FDA Sample 462746?

A. Correct; yes, sir.

Q. And if you go to the third page, you can see that it's another Digitek sample; correct? Very top in

the center?
A. Right.
Q. And just below that, they received this sample in April of 2008; right?
A. 4/3/08; yes, sir.
Q. And if you go back to the second page -- I'm sorry. Well, let's just go to the Lab Conclusion.
A. Uh-huh.
Q. Second page. Did it pass all the tests to which FDA subjected it?
A. Lab Conclusion, it meets specifications; yes, sir.
Q. Was this in a blister pack?
A. I'll have to read it, Matt.
Q. Third page, halfway down in the big "Summary of Analysis" box. Do you see that?
A. Yeah, I guess I do.
Q. All right. And I want you to assume that this is Actavis batch 70300A. Okay?
A. Yes, sir.
Q. Have you seen any information to indicate that that Actavis batch had out-of-specification tablets?
A. No, I did not. Matt, and to confirm your first question, it is in a blister, based on this

description.

Q. And I didn't ask you that last question on several of these batch exhibits; but have you seen any evidence to indicate that any of the batches I've asked you about with these FDA samples were out of specification?

A. Nothing that would -- nothing that would bring me to that conclusion.

Q. All right. So let's go to Exhibit 30.

Is it FDA Sample 462753?

A. Yes, it is.

Q. Was it collected in March of 2008?

A. March 21st, 2008; yes, sir.

Q. From a Wal-Mart in California?

A. Right; yes, sir.

Q. And the batch says, "8A 332."

Do you see that?

A. Yes, sir.

Q. And that is a UDL batch number, which corresponds to --

A. UDL is?

Q. That's Batch 70834A.

A. I'm sorry. What is UDL?

Q. You don't know what UDL is?

A. No.

Q. Okay. We'll get to that.
A. Okay.
Q. This is a Digitek sample, is it not? Exhibit 30? It's right --
A. Digitek, right. Got it.
Q. And I'd like you to go to the third page of the exhibit.
A. Got it.
Q. Is there a Lab Conclusion?
A. There sure is.
Q. What's the conclusion?
A. That they meet specifications for identity -- identification, dissolution and content uniformity.
Q. Do you have any evidence from anything in front of you to indicate that any tablets from this batch were out of specification?
A. No.
Q. Let's go to Exhibit 31, please.
And I'll represent to you when you get back to 2002, their records get a lot thinner.
Is this another 484 sample?
A. It looks to be.
Q. From March of 2002?
A. Yes.
Q. And the -- for Digitek?

A. Product description; yes, it is.
Q. Is there a Lab Conclusion in the center of the page?
A. It meets USP's uniformity of dosage unit specifications, but it says nothing about dissolution.
Q. Well, why don't you go to the very last test on the page?
A. There it is.
Q. What it does it say about dissolution?
A. There it is. Meets dissolution on -- I didn't read that far.
Q. You don't have any evidence that any of these tablets from that batch were out of spec; do you?
A. No, sir.
Q. Are you aware that at least this testing exceeds the recall parameter dates?
A. Well, this is -- is that based on this date, Matt, '02?
Q. Well, do you know when the recalled batches were first manufactured?
A. I don't know that date, to be honest with you.
Q. All right. Let's go to Exhibit 32, please.
Is this another FDA Form 484 sample?
A. Yes, sir.

Q. Sample 157504?
A. Yes, sir.
Q. For Digitek?
A. Yes, sir.
Q. Center of the page, what was the Lab Conclusion?
A. USP uniformity of dosage units. It looks like it meets. It also meets USP requirements for dissolution.
Q. All right. Exhibit 33, please.
Is this another FDA 484 Digitek sample?
A. Yes, it is.
Q. Sample 178890?
A. Correct.
Q. Now, in the Lab section, does it say anything other than "in compliance"?
Do you see where I'm talking about?
A. Yeah, yeah, right in the middle there, "in compliance." I don't see any other comment. It says that in two places.
Q. Okay. Would you assume that that's -- that it passed both content uniformity and dissolution?
A. I would, simply because this is the same laboratory that did the prior, and it uses the "in compliance," and it does note that it meets.

Q. Okay.
A. Even though it's absent here.
Q. All right.
A. Okay?
Q. So look at Exhibit 34, please.
Is that another FDA Form 484 sample report?
A. 178891, yes, it is.
Q. And -- for Digitek?
A. Correct.
Q. And halfway down the page, does it indicate in two different places that the product was in compliance?
A. That's correct.
Q. Now, have you read anything in any of the material that you have seen to indicate to you who UDL was?
A. I have to admit that I cannot remember UDL.
Q. All right.
A. To be perfectly honest, I think I've asked the question. I just do not remember the answer.
Q. From all the material that you reviewed from Actavis, did Actavis always package its product in bottles?
A. Everything I looked at went into bottles, yes, sir.

Q. All right. You know the manufacturing of -- and packaging of pharmaceuticals, so at some point what would -- what assumption would you make about how Digitek got into blister packs?

A. They would have had to have gone with a third party contractor to do that, if they didn't have the capability themselves.

Q. Okay. I want you to assume that that third-party contractor is UDL. Okay?

A. I got it.

Q. Did Novartis make any product in blister packs?

A. We were a European-based company, Matt. Every product was offered in blisters.

Q. Okay. What did Novartis do --

(A discussion is held off the record.)

A. Every product we made was made in blisters. We distributed in Europe.

Q. What did Novartis do to make sure that tablets would fit into blisters?

MR. MILLER: Object to form.

A. We would -- we would design the blisters such that it would fit within a normal range. What that means, Matt, was: We didn't custom-make blister tools. We made sure that our tablets were made to

engage, that would accommodate blister tooling downstream.

Q. Well, what would happen if by accident, Novartis made some double-thick tablets? Would they fit into your blisters?

A. This would be more of an opinion, I think, for me. I would think based on what I've seen in the past, some would, some wouldn't. I'm not trying to be evasive here.

Q. In pharmaceutical packaging, you want the blister to be relatively tight to the tablet; don't you?

And I'll give you two reasons why. Do you agree with me it should be tight to the tablet, relatively speaking?

MS. CARTER: Object to form.

A. In general I agree with you, Matt. I'm trying to think -- from my experience, I'm trying to picture some of it.

Q. Well, you don't want a lot of space --

A. No.

Q. -- because the tablet could bounce around and break; right?

A. We both agree to that. It's not going to rattle like a kid's toy. Okay?

Q. And if you use too much packaging, you are kind of wasting resources; aren't you?
A. Precisely.
Q. All right.
A. We are in agreement there.
Q. All right. Do you know anything about what UDL did to check tablet thickness of Digitek before it put it in blister packs?
A. No, sir.
Q. Okay. Could you look in the stack for Exhibit 35? It's right there.
A. Sure. It's right here.
Q. All right. Look at the first page. First of all, is this on Celsis Analytical Services letterhead?
A. Yes, Matt, that's what it says.
Q. Do you know who Celsis Analytical Service is?
A. I would just assume is a third-party analytical laboratory. That's all I can say. I have not heard of them myself.
Q. In the center, do you see the names of the three samples?
A. Digitek, yes, sir.
Q. Three different batches?
A. Yes, sir.
Q. And at the very bottom, the date is January

29th, 2007?
A. Yes, sir.
Q. I want you to flip back to Bates Page UDL011685. I skipped a few zeros. It's not very far back.
A. Yeah. Got it.
Q. Do you see that? Does it appear to you that this is the certificate of analysis for this product by Actavis?
A. That's what it says; yes, sir.
Q. All right. And then if you flip back to -- further, do you see that Celsis did some independent testing of this?
A. Yes, sir.
MR. MILLER: Now, when you say flip back a little bit further, do you have a specific page?
MR. MORIARTY: There's lots of pages, Pete.
Q. I would start at UDL11687.
A. Yes, sir.
Q. And go back. All right?
Does it appear to you from 11687 that this product passed the tests to which Celsis submitted it?
I'm sorry. That was a bad question.
From Page 11687, does it appear to you that -- that the product passed the tests to which

Celsis subjected it?

A. Based on these numbers, yes, Matt, it did --

Q. All right.

A. -- pass.

Q. Now let's go back to 11717.

A. Okay.

Q. Is that the certificate of analysis for a different batch than we just discussed?

A. Sorry, Matt. I went to the wrong page. Can we have that page number again, Matt?

MR. MILLER: 11717.

(A discussion is held off the record.)

Q. 11685. It's Batch 61100.

The one I'm now asking you about at 11717 is Batch 61097. Okay?

A. I got you.

Q. So we're up to a different batch; correct?

A. I got it now, yes, sir.

Q. All right. And if you go two pages more to 11719, does it appear to you that the product passed the tests to which Celsis subjected it?

A. Yes, it does.

Q. Let's go all the way back to 11746.

A. Okay.

Q. Is this the Actavis certificate of analysis

for yet a third batch, 60992A?

A. Yes, it is, Matt.

Q. And if you go two more pages, does it appear that the product passed all the tests to which Celsis subjected it?

A. Based on the information here, it met every requirement.

Q. Have you seen any evidence in any material that you reviewed to indicate that any of these three batches had out-of-specification testing by anyone?

A. These three batches, no Matt. I do not.

Q. Let's go to Exhibit 69. Is 69 in the stack?

(A discussion is held off the record.)

A. 69, got it.

Q. All right. Is this a UDL Lab document?

A. Yes, it is.

Q. And if you look a little bit way down, this is regarding Actavis Batch 80111A; correct?

A. Yes, it is.

Q. And if you go to the -- about the middle. It's UDL7655.

A. Yes, sir.

Q. Did they measure Digitek tablets in two dimensions?

A. Yes, they did.

Q. Were any of them out of spec?
A. I don't recall the spec off the top. Is it written here? I have to go back and look.
Q. It's at the very bottom.
A. There it is, I see it.
Q. Actually, that's not correct. That may be the range they found.
A. But just for our both's sake, I'll look at the batch record. Okay?
Q. Sure.
A. Is that okay?
Q. Oh, it's fine. Oh, yeah. If you think it's in there.
A. It's in the compression sheets.
(A discussion is held off the record.)
Q. Okay. The thickness range for 250 micrograms is 2.7 to 3.7 millimeters.
A. 2.7 to 3.7? So based on that, these fall well within mid range. Okay?
Q. All right.
A. And just for clarity, Matt, what I was -- this was -- I just put down a bunch of numbers because I have trouble remembering specifications. I just wrote them down on here. Okay? It's no big --
Q. Sure.

A. And I didn't have that either, just to be clear.

Q. Okay. Let's go to Exhibit 70, which I did not mark the other day. Here it is.

Is this another UDL Laboratories sheet?

A. Yes, it is.

Q. Regarding Digitek Batch 71034A?

A. Yes, it is.

Q. And if you go to a similar spot in this document, it's the last one, do you see the product dimension records?

A. Right.

Q. And this is for another 250 microgram batch?

A. I know all fall well within the mid range.

Q. All within spec?

A. All within spec, yes.

Q. Let's go to Exhibit 71. Here you go.

A. Thanks.

Q. And is this a UDL Laboratories sheet?

A. Yes, it is.

Q. Regarding Actavis Batch 71004A?

A. Yes, it is.

Q. And this is a 125-microgram lot; correct?

A. Correct.

Q. And if you assume that the thickness specs

for that product are two to three millimeters, did all these pass?

A. You pulled that right off the batch record, Matt?

Q. I guess you'll just have to trust me.

A. I'm good.

Q. It's in the ANDA.

A. And it's also right here, too.

Q. So --

A. The answer is -- the exhibit here shows that this result of thickness falls within the mid range of their specification thickness.

Q. Okay. Let's go to Exhibit 72.

Is this another UDL document?

A. Yes, it is.

Q. Regarding Batch 70175A?

A. Right.

Q. Please go to the same place. This is a 250 microgram batch.

A. Got it.

Q. Did all the 20 tablets that they measured meet the specs?

A. The specs being 2.7 millimeters to 3.7 millimeters; this batch falls right in the middle of the range.

Q. Okay. Let's go to Exhibit 73.
Have you ever seen this document before?
A. No, sir.
Q. Had you ever seen any of those UDL documents I just showed you?
A. No, Matt, I did not.
Q. Does this say, "UDL Internal Investigation Record"?
A. It sure does; yes, sir.
Q. Do you see that this was in -- let me find the date. On the last page, May of 2008.
A. Right.
Q. And can you tell from the first page of the -- this, that this investigation was done because there was a recall going on?
A. Just give me a minute, Matt.
Okay. "Class 1 drug recall nationwide," got it. "Is being recalled."
(A discussion is held off the record.)
A. Product recall is obvious based on this statement, yes, sir.
Q. And UDL investigated -- at the third page, you can see a complaint history with this product. Do you see that?
A. Just give me a sec.

Q. Well, I'll tell you what.

MR. MORIARTY: Let me withdraw that question.

Q. Let's go to the second page. Do you see that under "Investigation Summary," they have a section on receiving inspection records?

A. Yes.

MR. MILLER: Wait a minute. I'm not with you.

MR. MORIARTY: Second page, top.

MR. MILLER: Okay. Got it.

Q. And then there's a section called "Batch Record Documentation"? Do you see that?

A. Yes, I see it, Matt.

Q. Is there a section called "Examination of Retained Samples"?

A. Right. The copy starts to get a little fuzzy down there, but I can see that, yes.

Q. And then on the next page at the top, "Complaint History"? Do you see that?

A. Right.

Q. Now, if you were going to do -- I'm sorry. I'm not --

On the last page, it says "Stability records history." Do you see that?

A. Yes, I do.

Q. If you were going to do an investigation, are

these the kind of things that you would look at?
A. If I was aware that this was one of the put-ups that I had that was problematic. I think this would be a substantive piece of information. It would certainly give me a sense to -- of the tablet gauge.
Q. Okay.
A. Because certainly downstream packaging, especially in something as -- as punitive as a blister, it's important to know.
Q. Okay. And go to the last page. Do you see they have a "Conclusion"? Just above the signature?
A. Right.
Q. Do you see that?
A. "UDL is continuing a voluntary --"
Q. No, no. Above that.
A. I'm sorry.
Q. It says, "Conclusion." Do you see that?
A. Yes.
Q. It says, "Records reviewed, retained sample examination and complaint history for products and lots in question demonstrate no evidence of unusual events that could be related to the packaging of double the thickness tablets in unit dose blisters."
Do you see that?
A. I see it; yes, sir.

Q. Okay. Let's go to number -- Exhibit 83.

Good luck with this one. I want you to take a minute to look through that.

First of all, have you ever seen it before?

A. No, sir.

Q. All right. I'm going to walk you through this.

A. All right.

Q. Do you see that this is on UDL Labs letterhead?

A. Yes.

Q. From your own knowledge of the pharmaceutical industry, would a repackager have an obligation to do dissolution testing in order to assess whether their repackaging of the product had any effect on shelf life or stability?

A. That would depend on the product. Customarily you want to make sure that the environment in which you package the product doesn't affect it. In other words, it going to be there in bulk.

Q. Okay.

A. So in that case, you'd want to do everything necessary to assure that. Okay?

Q. So let's go back to -- let's go back to the first page, I guess. Is this a transmittal form?

A. Yes, that's what it says.
Q. And essentially what it is telling us is that on January 29th, 2007, UDL shipped Celsis Laboratories three Digitek samples. Is that right?
A. Yes, it is.
Q. And if we flip through the remaining pages, you see that on various other dates, UDL sent RD Laboratories in Missouri various other Digitek samples; is that right?
A. Right, yes. It looks like these are stability samples.
Q. Okay. So let's go back to the actual Results sections.
Now, I can tell you, Dr. Somma, that I have read this document and I think there are 33 batches of Digitek over the years that UDL sent to either Celsis or RD. Okay? You are welcome to count them if you'd like, but I just want to go through a few of them.
A. Okay.
MR. MILLER: What page are you on?
Q. Not all 33 of them.
MR. MORIARTY: I am on UDL11369.
MR. MILLER: Okay.
Q. Do you see that this is a stability test result?

A. Yeah, yes, sir.
Q. For, on the right-hand side in the corner, Actavis Lot 70834A? Upper right-hand corner.
A. The other right. 703 -- 70834A, yes, sir.
Q. And the initial testing in October of 2007 showed an assay of 97.3 percent; correct?
A. Yeah, yes, sir.
Q. Are you familiar with this kind of stability test reporting?
A. Yes, sir.
Q. Would you assume that the initial October of 2007 was what Actavis tested at the time of finished product testing?
A. That -- is this a confirmation -- is this aligned with their results?
Q. I don't know. I'm just asking what you know about this. If you don't know, I don't want you to guess.
A. That I couldn't answer, then.
Q. Okay.
A. If they are both working with the same spec and the same method and it's been transferred, it should be right within -- right within experimental error.
Q. Okay. So let's go to the next page, UDL

11370, and in the upper right, this is Batch 70386A.

A. Right.

Q. Correct?

A. Uh-huh.

Q. And on this page in May of '07, the assay result was 97.1. Is that correct?

A. 97.1, yes, sir.

Q. Percent?

A. Percent. Okay.

Q. And if you look at the bottom on the left, it says the manufacturing date of May of '07.

Do you see that?

A. Uh-huh.

Q. That's yes?

A. Yes, sir. And I see --

Q. And a manufacturer's assay of 97.1 percent; correct?

A. Right.

Q. Is it reasonable to conclude, therefore, that this top part where the initial -- it lists the initial assay, is the original Actavis assay when it made the batch?

MR. MILLER: Object to form.

A. In my experience, what happens is your Time Zero is usually not repeated. That would be -- it

could have been data that was there, and they just used that as Time Zero.

Q. Okay.

A. Okay? So Matt, that would be why they're the same.

Q. Right.

A. But, again, I wouldn't know that for a fact. That's my experience.

Q. When UDL gets the certificate of analysis from Actavis, it has the assay results with it?

A. Right. So that would be Time Zero.

Q. Okay. So the next section says, "Shelf life testing, three months, assay result 97.2."

Do you see that?

A. Yes, sir.

Q. And that's within the specifications. Is that right?

A. It sure is, yes, sir.

Q. Now, if we flip back through every one of these pages, is the format essentially the same, where the Actavis lot is in the upper right-hand corner?

A. Yes.

Q. And the assay results to which either Celsis or RD tested the Digitek are contained in these grid charts. Is that right?

A. Yes, sir.
Q. All right. I would like you to flip through all those pages and tell me if there was ever a stability failure of Digitek when tested at the request of UDL?
MS. CARTER: Object to the form.
A. On several occasions, Matt, these are dissolution results at the S2 level. My experience, those would precipitate an investigation. But did they fail? No.
I'm looking at specifically Page 11373. It notes it as an S2. That just means that you increase the sampling.
Q. Okay.
A. But, again, not knowing that part of it, that usually precipitates an evaluation. It is not per se a failure. Okay?
MR. MILLER: If we're going to leave this document, it might be a good time for lunch.
MR. MORIARTY: Let me finish up.
A. When I'm done --
MR. MORIARTY: Let me finish up my section. I have another exhibit. And maybe one or two more questions.
MR. MILLER: Okay.

(A discussion is held off the record.)
Q. Do you see any stability failures?
A. Other than those comments I made about S2, there are no stability failures in here.
Q. And stability testing is doing assay of the product over time; is it not?
A. Yes, it is.
Q. Okay. I want to hand you what I had marked as Exhibit 84. This is another UDL document.
Have you ever seen this before?
A. No, sir.
Q. Had you ever seen all that stability testing before?
A. This? I never looked at that.
Q. All right. This is a memo, is it not, dated May 5th, 2008?
A. That's correct.
Q. And if you go to the second paragraph, third line down, it says, "UDL tests the product for potential and dissolution. In reviewing the data for both strengths of Digitek, the potency showed no apparent trending."
Let me stop there. Have you seen anything in the documents that I have given you so far to indicate there was any adverse trending to the Digitek data?

MR. MILLER: Object to form.

A. To answer it accurately, Matt, I would have to look at all of that information together. My sense is: Based on those numbers I looked at, they were all within the mid to high 90s.

Q. All right. Do you have any reason to disagree with the person from UDL --

A. Absolutely not.

Q. -- who did this?

A. Absolutely not.

Q. The last sentence says, "Overall both strengths of this product have shown no remarkable stability data through the assigned expiration date in the unit dose package."

Do you have any reason to disagree with that?

A. Not at all.

Q. Now, I've shown you -- We know that Actavis tested all this and it was within spec when they tested it. And I've now shown you Quantic batch record review materials. I've shown you FDA testing of the product. I've shown you testing done at the request of UDL; correct?

A. Uh-huh; yes, sir.

Q. We've spent about an hour just going over testing of Digitek; right?

A. Yes, sir.
Q. Do you have any evidence, any documents, any test results to indicate that there was Digitek in the hands of consumers that was outside its labeled specifications?
MR. MILLER: Object to form.
A. Nothing other than the Batch 70924A.
Q. All right. Do you have any evidence that any tablets from --
MR. MORIARTY: Let me withdraw that.
Q. Do you have any evidence that out-of-specification tablets from Batch 70924A made it to the hands of consumers?
A. The batch was tested according to the C of A. According to the certificate of analysis, the batch met requirements. So the answer is: That batch met requirements, yes.
Q. Okay. Well, that batch was -- the investigation of that batch was for double-thick tablets; correct?
A. That's correct, sir.
Q. Not for tablets of normal size with varying potency; right?
A. That's correct.
Q. Do you have any evidence from any document

you have seen, any deposition testimony you have seen, that an oversized tablet from Batch 70924A made it to the hands of a consumer?

A. I would have to say no.

Q. All right.

MR. MORIARTY: That's a good time for a lunch break.

THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 12:29 p.m. This is the end of Tape Number 3.

(The luncheon recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 1:38 p.m. This is the beginning of Tape Number 4.

Q. Dr. Somma, have you ever consulted with my client, Actavis?

A. No, sir.

Q. Have you ever consulted with Mylan?

A. No, sir.

Q. Now, earlier I went through all that 484 testing from the FDA, and by my count, seven of the batches that they tested are what wound up being the recall batches. Okay? Which is about 4.6 percent.

A. Yes, sir.
Q. Do you have an opinion as to whether that is a statistically significant number?
MR. MILLER: Object to form.
A. Is that statistically significant, the batches that were recalled; correct, Matt?
Q. Yes. Seven out of 152?
A. Whether it is statistically significant or not, it's hard for me to say. Is it representative of what was made? I don't think so.
Q. Why isn't it representative of what was made?
A. Well, to get back to what I had said before, bottom line on all of this was: I have not seen an investigation which resolved the root cause of the things I observed in these other batches, such as some of the blend uniformity issues, things like that.
Other than that, based on the merit and the information in front of me, those are -- those batches passed, yes. And they were confirmed by two -- two sources.
Q. And by my count Celsis, one way or another, tested 11 out of 152 batches, which is about 7.2 percent. Is that statistically significant?
MR. MILLER: Object to form.
A. I would say the same answer again, you know.

Q. And if you add those two together and take out any duplicates that may have been tested by both Celsis and FDA, it's 16 out of the 152, which is ten and a half percent.

Is that statistically significant?

MR. MILLER: Object to form.

A. It's hard for me to answer that question yes or no.

Q. Do you think that FDA's testing seven out of 152 recall batches provides a high degree of assurance --

A. No more than any -- I'm sorry.

Q. -- that those seven batches at least met their specifications for identity, purity, and potency?

MR. MILLER: Object to form. .

A. No. Again, those seven batches -- no more does that testing or Celsis's testing represent the fact that all of the batches in question don't have some problem. It meant that that sample using those specifications at that time met requirements.

It gets back to the point I made earlier: That this is a totality, it's a continuum, it's not just a speck in the results.

Q. All right. Well, have you seen any FDA

documents that someone said that there was a total failure of the quality system?

A. I believe in this Exhibit 26, Matt, there is a statement. I don't know if it says "total failure."

(A discussion is held off the record.)

A. I'm referring to Exhibit Number 26 in response to Matt's question. That was the only -- this is the point that I had seen. That was a comment from the FDA, as far as their quality system goes.

Q. Well, if somebody else were to have said there was a total failure of Quality, do you think that's an overstatement, given the fact that UDL and Celsis have independently confirmed that at least those batches, when tested, met the specifications?

MR. MILLER: Object to form.

A. Again, my -- my --

Q. That one's a yes or no. Do you think it's an overstatement?

A. No.

Q. Explain your answer.

A. I think that statement is based upon what I say the whole picture, not just a series of specifications -- a series of batch results. This speaks to things in total, and that gets back to my comments about investigations and analysis of other

mitigating circumstances.

Q. Well, you know there was an all-products recall a month or two after the Digitek recall; correct? Do you know that?

A. All products were recalled, yes, sir.

Q. And do you know those were not to the consumer level?

A. That I didn't know, sir.

Q. Did you think when you got here today that all the products were recalled to the consumer level?

A. No, no, sir.

Q. You didn't give it any thought one way or another?

MR. MILLER: Object to form.

A. Not that it was pertinent to what I was looking at in this particular case.

Q. Okay. Did the FDA ever make a specific finding in any document that you've ever seen that Digitek was adulterated?

MR. MILLER: Object to form.

A. Well, getting back to the question -- to the definition of "adulterated," I would say, based on the broad-based comment in Citation 1, that based on their definition, those -- Digitek would be adulterated by their definition.

Q. That's not what I asked you.
A. Okay. Then please ask again.
Q. Did they make an explicit statement anywhere that Digitek was adulterated?
A. And, again, I just think if it is noncompliance, by their definition it is adulterated.
Q. I want you to find me a statement in any of the paper in front of you that says -- from the FDA, that Digitek was adulterated. Explicit statement. Not you inferring or --
A. Understood.
MR. MILLER: I'm going to object to form.
A. I'm looking at this Exhibit 91, Matt. And to answer your question point on about they say it's adulterated, this is -- in this particular statement here, it doesn't come right out and say that, "adulterated," it does not say that. Okay?
Q. Okay. Have you seen any FDA statement at all specifically finding that there was out-of-specification Digitek in the hands of a consumer between 2004 and 2008?
A. I think the field action that recalled the batches speak to that point, or not? Did I misunderstand that? By recalling of batches, isn't that what that means, that they thought that that

happened?

Q. Sir, I thought you told me a number of hours ago that you could recall batches of pharmaceutical product for a number of different reasons; correct?

A. Yes, you can, right.

Q. And defective, actual out-of-spec tablets in the hands of consumers may or not be the case; right?

MR. MILLER: Object to form.

A. May or may not be the case, correct.

Q. FDA could recall pharmaceutical products because the label was on crooked?

A. That's correct.

Q. Or they didn't like the way the plumbing in the plant was; correct?

A. That's correct.

Q. All right. So what I'm asking you: In all the ocean of material that you have reviewed, do you find any explicit statement by the FDA that there was out-of-specification Digitek in the hands of consumers between 2004 and the spring of 2008?

MR. MILLER: Object.

A. And, again, to that, Matt, what I would have to answer is that they found noncompliance to procedures, they found information about blend uniformity. Nothing that specifically speaks to

defective tablets being distributed.

Q. And just because there were some blend uniformity out of specs that were the subject of an FDA 483 because of the investigation technique, does not mean there was out-of-spec Digitek in the hands of consumers; does there?

MR. MILLER: Object to form.

A. That's hard to say, Matt, because they never did the investigation as I would have understood it, to be perfectly honest.

Q. All right. But you have all this information available, and you haven't seen any evidence of out-of-spec Digitek in the hands of a consumer; have you?

MR. MILLER: Object to form.

Q. You told me that before lunch?

A. Right, right.

Q. Every piece of evidence you have seen regarding testing of Digitek has been within compliance?

A. Testing -- Absolutely.

Q. Do you have any idea of what percentage of pharmacies in the United States still count out tablets by hand?

A. Oh, I practiced pharmacy for awhile and every

one that I worked in, we counted by hand. So my guess would be -- the big box stores, whatever percentage they are, counting automatically. That would be my guess.

Q. How does a big box store go from a thousand-count bottle of tablets on a shelf into a vial with an automatic counter? Or are you talking about mail order pharmacies?

A. No, sir. They would fill a tablet counter up with a thousand tablets, type in the number they need --

(A discussion is held off the record.)

A. Set the counter and then the machine counts the tablets.

Q. And what percentage of pharmacies in the United States use automated versus hand counting?

MR. MILLER: Object to form.

A. That would be a complete guess on my part. It's got to be a small percentage.

Q. You mean it's a small percentage that use automatic?

A. Yes, sir.

Q. So if tablets were out of specification by size, that's what's known in the industry as a visible defect; is it not?

A. Visible -- visual defect, yes.
Q. And it is at least theoretically possible that the pharmacy level, when tablets are hand counted, is a point at which tablets that were extra thick could be detected; correct?
MR. MILLER: Object to form.
A. I would have to agree to an extent; but saying, based on my pharmacist's background, I was not looking for thick tablets. My objective was to make sure that the prescription was filled adequately, that the all -- that all of the paperwork was filled out, and that the clinical profile of the patient was done. And a lot of cases nowadays, it is done by a technician.
Q. All right. Well, some human being was used to counting out tablets; right?
A. Right.
Q. Have you ever actually seen and touched a Digitek tablet?
A. No, sir.
Q. I'm sorry?
A. No, sir.
Q. If a tablet that was supposed to be between two and three millimeters was double thick, so it was somewhere between four and six, is that a visual

defect that a reasonable technician or pharmacist would be able to detect when counting out a prescription of 30 to 100 tablets?

MR. MILLER: Object to form.

A. I don't think so, because when you put these into a counting tray, they all lay down flat. How would you able to determine -- determining height of tablets, Matt, across a bed of tablets is very difficult. You would actually have -- it would have to be on your side.

So my guess is that that's pretty tough to do, just from having done it myself.

Q. Well, if there was one double-thick tablet in there, it would be sticking out like a skyscraper, right?

A. Like a skyscraper, yeah. That you -- Unless you -- in that case, if it was that thick. But again, three millimeters, double, six; my guess is you probably would see that.

Q. All right.

A. I'm not saying I would see that.

Q. Did you say earlier you had not reviewed any adverse event reporting data in this case?

A. That's correct.

Q. Do you have any opinions about adverse events

with Digitek?

A. No, sir.

Q. Did you ask Mr. Miller or Ms. Carter how many of the plaintiffs in this litigation had had their tablets weighed or measured?

A. No, sir. I looked for the information in the information provided.

Q. All right. You didn't see any plaintiffs who had double-thick tablets; did you? Or even extra-thick tablets?

A. I didn't see -- I didn't see any information that said that at all. Okay?

Q. In a piece of litigation like this, and I know you are new to this process, but if they had evidence that their clients had extra-thick tablets that were outside the specifications, do you think it's the kind of material that they would give you to review?

A. I would think so.

Q. Have you seen any reliable reports that an extra-thick tablet was detected by a pharmacist in 2005, 2006, 2007 or 2008?

A. We had discussed that before, as I recall. I thought I did, but I was not able to recover it.

Q. Well, I said reliable report by a pharmacist

of an extra-thick tablet in 2005, '06, '07 or '08.

MR. MILLER: I'll object to form.

A. We just -- I'm going to look again.

I read it, Matt, and I cannot find it.

Q. You believe you have a report, a reliable report from a pharmacist that indicates that they found a double-thick tablet in the years I just mentioned, '05 through '08?

A. As I recall, the report was about a pharmacist finding a tablet, and the year I believe was '04.

Q. Is that the one -- Well, wait a minute. I said '05 through '08 three times.

Do you have such a report?

A. That's -- as I'm trying to think through it, I cannot locate it here.

Q. Do you think there is one? Now, we discussed one this morning about this nursing home, and you told me that it wouldn't be reliable given everything I asked you about it.

A. Right, right.

Q. I'm asking about a different question. A reliable report from a pharmacist in 2005, '06, '07 or '08 indicating that they had an extra-thick Digitek tablet.

MR. MILLER: Object to form.

A. Nothing that I can produce, no, sir.

Q. Can you look for Exhibit 21 in the stack, also known as Plaintiff's Exhibit 128?

Have you seen this document before?

A. Yes, sir.

Q. This is the extra-thick tablet investigation. The investigation was conducted in 2004; correct?

A. Yes, sir.

Q. And you see in here that somehow Actavis or Amide at the time was able to figure out that that came from a batch made in 2003; correct?

A. Yes, sir.

Q. Did the company alert the FDA to this event through what's known as a field alert report?

A. I don't know, Matt.

Q. Okay. I'd like you to look at Exhibit 20. It should be in that stack.

Have you seen that document before?

A. I believe so.

Q. It's an EIR from 2004. Is that correct?

A. Yes, sir.

Q. I'd like you to go to Page 4, please.

A. Uh-huh.

Q. Now, first of all, in order to be operating

under a consent degree -- decree, do you have to be in compliance with cGMPs?

A. Absolutely. You have to be in compliance with cPMG's if you make a product that's subject to human consumption.

Q. All right. So in the first paragraph, under "History of Business Operations" --

A. Right.

Q. -- four lines down, there is a sentence that says, "The consent decree was lifted in 2001 following successful demonstration of sustained cGMP compliance."

Do you see that?

A. Yes, sir.

Q. Do you have any reason to disagree with the FDA about that?

A. No, sir.

Q. Let's go to Page 6. Under the Field Alert Reporting section.

A. Uh-huh.

Q. It says, "A final field alert report for NDA 40-282, digoxin tablets .25 milligrams was filed during the reporting period."

Do you see that?

A. Yes, sir.

Q. And if you read on, what they're referring to is the investigation contained in Exhibit 21. Is that right?

MR. MILLER: Take your time and read it.

A. Got it. Okay.

Q. Am I right?

A. Yes, sir.

Q. So go down ten lines from the top of that paragraph. It says, "No additional complaints or reports of thick tablets have been received for this high volume product."

Do you have any reason to disagree with the FDA about that?

A. I don't see why, no.

Q. Okay. "The event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence."

Do you agree with that?

A. Uh-huh, yes, sir.

Q. Now let's go to Page 9. In the section called Complaints, the second paragraph.

It says, "A larger number of complaints was also noted for digoxin tablets; however, it is the highest volume product according to the list of batches produced per year."

Do you have any reason to disagree with that?
A. No, sir.
Q. "There were also no trends observed for the types of complaints."
Any reason to disagree with that?
A. No, not at all.
Q. Was FDA satisfied with the investigation of Exhibit -- that's embodied in Exhibit 21?
MR. MILLER: Object to form.
A. Let me just change my glasses.
Based on the data I have in front of me, they're satisfied, yeah.
Q. There was never a 483 or a warning letter about that incident or its investigation; is that correct?
A. I'm just making sure this 483 is not it. This one, I'm just looking at one from May back. No. The answer is: There is nothing as a result of this.
Q. All right. Now, before the lunch break you told me you didn't have any evidence of out-of-spec tablets getting in the hands of consumers. I want to talk a little bit more about that. Okay?
A. Yes, sir.
Q. Do you have an opinion --
MR. MORIARTY: Withdraw that.

Q. Let me start over. Let's just talk about the recalled batches, and let's assume there were 688.2 million tablets in that grouping; okay?

A. Okay.

Q. Do you have an opinion to a probability as to how many of them were outside their specifications?

A. I think when we discussed, we said that none of those that were released were out of specification, as I recall. The probability of -- of them being out of specification, which means tablets which were not tested, in other words a batch is made of two million, you test 100. So the probability of one that is not tested sneaking out is within the realm of possibility, yes.

Q. Okay. Do you know that -- in your work at Novartis, I assume you talked to scientists, people all the time; right?

A. Right, okay.

Q. You are familiar with the terms "probability" and "possibility;" right?

A. Right, everything is possible, correct.

Q. And probability is more likely than not; correct?

A. It's probable, it's likely.

Q. Okay. So what I'm trying to find out, and my

clients are entitled to know, is whether you have an opinion to a reasonable probability as to how many of the 688 million tablets among the recalled group were outside their specifications? Do you have such an opinion?

A. I have an opinion based on a review of the information I've seen.

Q. Is it an opinion to a probability?

A. To a probability? Based on the information I've seen, and the lack of investigation and rigor that addressed the problem, that it is highly probable that something was distributed and not caught; caught in the testing sense.

Q. Okay. How many of the 688 million tablets in the recall group were likely outside their specifications?

A. That's very difficult to say.

Q. You have no opinion to a probability as to a number?

A. I think it's hard to put a number on it, to be perfectly honest, because what we are talking about in this particular case, my opinion is they did not do a rigorous enough evaluation of things to assess that they even had a problem. In that case, the probability could be as high as 100 percent and could

be as low as zero. Without the analysis and the information to make that assessment, Matt, I can't say for sure.

Q. All right. So you would be speculating to put a number; right?

A. I think that would be a safe bet, yeah.

Q. Okay. So -- And I can keep -- I'm going to keep asking you these questions, because I need to know, not because I'm trying to be a pain in the neck.

But if a tablet was outside its specifications, there are only two possibilities there; one is it's high outside the specs or low outside the specs; correct?

MR. MILLER: Object to form.

A. Correct. Okay.

Q. Are there any other possibilities besides -- if they're outside the specs, are there any other possibilities besides high or low?

MR. MILLER: Object to form.

Q. Answer me as a scientist.

A. As a -- if there were -- they're either outside the spec, high, or low outside the spec, correct, correct. There's a range.

Q. Okay. All right.

Ignore the man outside the curtain for right

now.

MR. MILLER: Do not ignore the man outside the curtain. Disregard that.

MR. MORIARTY: Behind the curtain, I should say.

Q. So do you have any opinion to a probability as to how many of the recalled Digitek tablets were outside the specifications, low?

A. I would have --

MR. MILLER: Excuse me. I'm going to object to the form.

Q. On the low side?

A. I would -- it's -- again, I'm not trying to be evasive. It's just difficult to answer that as if on the high side. The question is -- I can't -- I can't assign a number to that.

Q. All right. My first question was: Did you have an opinion as to whether they were outside the specs as all, and we covered that.

A. Yes, we did.

Q. Now I'm getting into the two possibilities.

A. Right.

Q. And if you don't have an opinion to a reasonable probability, that's all you have to tell me.

A. Okay.
Q. So you don't have an opinion to a probability of how many were outside the specifications on the low side; correct?
A. No, sir.
MR. MILLER: Object to form.
Q. Do you have an opinion to a reasonable probability how many were outside the specifications on the high side?
A. No, sir.
Q. And it matters how low or how high; correct?
MR. MILLER: Object to form.
A. With --
Q. I'll rephrase my question.
If you were doing an investigation for a pharmaceutical company --
A. Right.
Q. -- whether it was Novartis or one of your consulting clients, and they had been releasing product that was outside the specifications, would you as a scientist want to know how far outside the specs they were?
MR. MILLER: Object to form.
A. Well, I think -- let me make sure I --
Q. Yes or no. Would you want to know that?

A. I wouldn't expect them to release anything outside of spec.

Q. That's not what I'm asking. You were called in as a consultant and somebody says, "We accidentally made some tablets that were outside the specs."

A. Oh, okay.

Q. It's a done deal; okay?

A. Right.

Q. You are called in as the consultant to do an investigation. Do you as a professional want to know how far outside the specs they were?

A. You have to do an analysis for trend, is it high, or is it low, yes.

Q. So do you have an opinion -- if there were by chance any tablets outside the specifications low, do you have any opinion as to how low outside the specs they were?

MR. MILLER: Object to form.

Q. To a probability?

A. Not until I see the information, I guess. It's hard to say, you know.

Q. Okay. But you haven't seen any such information about tablets outside the specs at all; correct?

MR. MILLER: Object to form.

A. In this particular case, no. They have -- in other words, I have asked for the information. I haven't seen any of that information, right.

Q. On the other side, do you have any opinion to a probability as to how far outside the specs high any Digitek tablets might have been, if there were any?

MR. MILLER: Object to form.

A. No, for the same reason I couldn't understand on the low side.

MR. MORIARTY: What's the basis for your form objection? I want the chance to cure it.

MR. MILLER: It's vague and misleading. Perhaps the expert does, but I don't know what specifications you were asking about.

Q. Outside any specification: Weight, thickness, active pharmaceutical ingredient. Did you understand my questions?

A. Yes.

Q. Okay.

A. To be real -- I want to-- that's my -- I understand what you are talking about. It doesn't matter -- A spec is a spec. I apologize.

Am I supposed to have clarified that?

Q. No. You and I understood one another perfectly. Okay.

Now, I assume, Dr. Somma, from reading your report and listening to what you are saying today that because of some cGMP violations, you have concerns about Digitek production. Am I correct about that?

MR. MILLER: Object to form.

A. There are -- the concerns I have are the --

Q. Yes or no?

A. Yes.

Q. Do you have concerns?

A. Yes, I do. Oh, I'm sorry. Yes, I do.

Q. And from a regulatory standpoint, when you are looking from the cGMP standpoint, there are findings in the FDA -- these FDA documents that lead you to conclude, and led the FDA to conclude, that Digitek may have been adulterated. Is that correct?

MR. MILLER: Object to form.

A. Yes.

Q. All right. But as we covered before, "adulterated" does not necessarily mean that the tablets were, in fact, outside their manufacturing specifications. Is that right?

MR. MILLER: Object to form.

A. "Adulterated" means -- could mean things that are major-major or minor, yes; not outside the specifications.

Q. So when we get specifically to Digitek, and I'll talk about the recall in more detail in a minute; FDA would have every right to ask Actavis to recall the Digitek within the expiration date just because they believed the investigation of 70924 was substandard. Is that right?

MR. MILLER: Object to form.

A. That's certainly within their right, yes.

Q. Even if there was no proof whatsoever that actually out-of-spec tablets made it to pharmacies and consumers. Is that right?

MR. MILLER: Object to form.

A. Could we go through that one more time, Matt? I'm not trying to be stupid.

THE WITNESS: Can I have that question again, Mark?

MR. MORIARTY: Mark, you are going to have to read that last one back.

(The question is read.)

A. Yes.

Q. So if I ask you a different way, do you have an opinion to a reasonable probability how many Digitek prescriptions were filled which contained as low as one out-of-specification tablet? Do you have an opinion to a probability on that subject?

A. That would fall -- that falls back into: Is it going to be low or is it going to be high. I guess my opinion is it's likely that something could be there. As far as a percentage, Matt, no.

Q. Now, wait.

A. Run it by me again.

Q. All along you have told me you have no opinion to a probability, this is what I'm hearing from you. Okay?

A. Right.

Q. Maybe Peter hears it differently.

A. Right.

Q. I'm hearing you have no opinion to a probability, a likelihood, that there were defective tablets in the hands of consumers at all?

A. Right.

MR. MILLER: Object to form. Misstates previous testimony.

Q. So I'm asking it from a different angle to make sure I have it all straight.

Do you have an opinion to a probability about how many people received any prescriptions with any defective, outside-of-specification Digitek tablets in them?

(A discussion is held off the record.)

A. No. I was still thinking about the spec thing, sorry.

Q. If there were tablets outside the specifications -- Okay? -- and let's just assume for right now that they were extra thick, and that because they were extra thick, they were outside the API specs on the high side. Okay? Let's just make that assumption for right now.

A. Okay.

Q. All right? If that were true and they went out into the marketplace, wouldn't it be likely at some point that collectively a pharmacist, a consumer, UDL, Actavis, FDA, Celsis Labs, a doctor or a hospital would notice something?

A. That's --

MR. MILLER: Object to form.

Sorry. Go ahead.

A. That's assuming that those systems are not set up to be challenged to find defects. Your system itself is supposed to be self-limiting, and your supply chain and distribution aspects are not meant to catch problems. Pharmacists and professionals in the distribution chain, if you are lucky, they are going to be vigilant and catch it. Have they been calibrated or are they checked?

You can't rely on that, is my opinion.

Q. I'm not asking you, Doctor -- or Dr. Somma, if you rely on that prospectively.

A. Right.

Q. I'm asking: After the fact; okay? Again, let's get back in. You are at Novartis and you have been called in --

A. Right.

Q. -- to one of your pharmaceutical clients. And somebody says, "I think we may have released tablets that are too thick, and if they are too thick they may have been outside the API specs;" okay?

A. Right.

Q. There are things to look at once the tablets leave your facility to see if, in fact, there were out-of-specification tablets; right?

A. These are --

Q. Yes or no? Things you can look at.

A. Things that you can look at, yes.

Q. All right. So one thing you might look at is: Did a repackager find any. Right?

A. Right.

Q. That's one thing you might look at.

A. Right, yes.

Q. And FDA tested tablets. Did they find any?

A. Right.
MR. MILLER: Object to form.
Q. And pharmacists would be counting these out and distributing them; did they find any? Correct?
A. Correct.
Q. You are continuing your investigation; right?
A. Right.
Q. You are nodding yes?
A. Yes, I'm hearing you. Sorry.
Q. And then, of course, consumers get them; and they could either notice it because it looked different than other tablets --
A. Yes.
Q. -- or they might get sick; right?
A. Well, we have assumed they would get sick, yes.
Q. But these are things that a reasonable investigator would look at; right?
A. Uh-huh.
Q. Is that yes?
A. I would ask the questions, and to be perfectly honest, I probably wouldn't go beyond asking this Celsis and the packager. I mean, I'm -- in my opinion -- my personal opinion, that's reaching when you try to rely on pharmacists as I had mentioned

before. But I'm okay with you right out into the packaging part, yeah.

Q. But if you are desperately seeking information, any shred of proof, you would want to go all the way to the consumers; wouldn't you?

A. Yes, sir.

Q. You might look at Poison Center statistics to see if they'd noticed a spike in digoxin toxicity?

MR. MILLER: Objection to form.

Q. Would you do that?

A. It sounds like a great idea. I would not have thought to do that, yes.

MR. MORIARTY: What was the matter with the form on that?

MR. MILLER: Scope. Excuse me. Objection, scope.

Q. Could you look for Exhibit 37, please?

Now, I am missing an exhibit, I think. Somewhere in this should be the recall press release.

Have you ever seen the recall press release of Digitek?

MR. MILLER: It's not that document. He pointed that document out, but that's not the document.

Q. I'll get to this one in a minute.

But have you seen the recall press recess of Digitek?

A. I don't recall reading it, Matt, no.

Q. What is your understanding of why Digitek --

I'm sorry. Let me rephrase that.

What is your understanding of what the FDA approved recall notice says about why Digitek was recalled?

MR. MILLER: Object to form.

THE WITNESS: Mark, read that question to me again, would you? If you don't mind.

Is it okay? I'm sorry.

(A discussion is held off the record.)

(The question is read.)

MR. MILLER: Again, object.

A. I haven't seen it, so I don't -- I can't really say.

Q. Okay. Here's Exhibit 36. It's the recall press release. I want you to take a look at that, and then if you don't mind, hand it back to me.

A. Sure thing.

Q. Because I seem to have coughed up all my copies of it.

Are you done reading it?

A. Yes, sir.

Q. May I have that back, please?
A. Sure. Here you go.
Q. It says here, "The voluntary all-lot recall is due to the --"
MR. MILLER: I was trying to have a copy in front of him so he can read along with you.
MR. MORIARTY: Oh, that's fine. I appreciate it.
Q. "The voluntary all-lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released."
Do you see that?
A. Yes, sir.
Q. Do you have any reason to disagree with that FDA-approved press release?
A. No, sir.
Q. And twice in that sentence that I just read, they use words connoting some degree of speculation. Is that right?
MR. MILLER: Object to form.
A. Yeah. "Possibility," "may have," yeah.
Q. Now, you can take a look at Exhibit 37.
A. Okay.
Q. Go to the third page. This is the recall package. Do you know what a recall package is?

A. I'm not familiar with all its content. I've heard of it.

Q. Have you ever seen this document before, Exhibit 37?

A. In the -- In the spirit of what I investigated, Matt, I didn't look at stuff -- this stuff, like the recall package. I didn't look at that.

Q. Did you look at Exhibit 36, the recall press release?

A. No, sir.

Q. If you go down to "Reason For Recall" in Roman numeral III, it says, "Digoxin tablets exceeded the thickness specifications."

Do you see that?

A. Okay. Yeah. I got it.

Q. Now, have you seen anywhere at all any indication from FDA or from my client, Actavis, that this recall of Digitek in April of 2008 was for normal-sized tablets with varying amounts of the active pharmaceutical ingredient?

A. This clearly notes "tablet thickness."

Q. Now, I'm done asking you about that.

If you were called in as you were with one of your private consulting clients to analyze a thick

tablet situation --

A. Yes, sir.

Q. -- typically you would think that that would be a tablet press issue. Is that right?

A. You'd want to -- you'd want to start at that point. It's the most likely.

Q. Okay.

A. Yes.

Q. And when you are looking for the cause of the extra-thick tablets, what you hope to get to is what you in the business call a root cause; right?

A. That's correct.

Q. So for a wild example, it could be a die set inappropriately calibrated; right?

A. Agreed.

Q. Okay. And that is --

Now, a normal-sized tablet with varying active pharmaceutical ingredient is a different or potentially different problem; isn't it?

A. Absolutely.

Q. So when you start looking for a root cause to that kind of problem, you have to go back to the mixing, the blending, the tabletting? You have to go back to all of it; correct?

A. The non-homogeneity in a tablet, yes, Matt.

Q. And extra thick tablets and tablets of normal size with varying potency are really, when you get down to it, from a professional's end, different kinds of defects. Is that right?

A. I see them -- this is why -- it's not going to be yes or no.

If the thing was uniform, the thick tablet and non-uniform tablet, that problem is one and the same, because that thickness is going to be more potent, let potent. We don't know that in this particular case. In this particular case that is thick, but we don't know why or how much.

So the answer is -- to answer your question specifically, there are two different cases here.

Q. Okay. And the FDA would know the difference between those kind of problems; right?

A. You would hope.

Q. You would hope.

A. Okay.

Q. And so when the FDA approved the recall press release and the recall package announcing that this recall was for the possibility that double-thick tablets may have been commercially released, it has a little bit more meaning just beyond those simple words; correct?

A. Presumably --
MR. MILLER: Object to the form.
MS. CARTER: Object to the form.
A. To me it does, yes.
Q. Okay. To you as a professional in the pharmaceutical industry, it does?
A. Right. That's what I'm saying.
Q. And as far as you can tell from all the material here, FDA did not cite or warn Actavis about Digitek that was normal in size, but outside its active pharmaceutical ingredients specifications. Is that right?
MR. MILLER: Object to form.
A. Yeah, Digitek tablets, no. The only thing was blend stuff that we talked about before.
Q. All right. Did the FDA ever ask Actavis to recall Digitek for blend uniformity issues?
A. Not to my knowledge, no.
Q. I want to show you what's been marked as Exhibit 38.
A. Okay.
Q. Have you ever seen this before?
A. It doesn't look familiar.
Q. It's a printout from the FDA's website.
A. Okay. I'm not a -- I don't customarily go

there and read stuff like this. I'm sorry. Okay?
Q. Okay.
A. Yeah.
Q. Well, once you were engaged in the Digitek litigation --
(A discussion is held off the record.)
Q. Once you were engaged in the Digitek litigation, even though you didn't customarily go to the FDA's website, did you do so to see what they said about the Digitek --
A. No, sir.
Q. -- recall?
A. No, sir. I went there to make sure that I had as much information as I needed about guidances in the area of uniformity.
Q. Okay. This is from a section of the FDA website that talks about facts and myths about generic drugs. Do you see that at the top?
A. Yes, sir.
Q. And then generally it has a fact --
MR. MORIARTY: I'm sorry. I'm going to withdraw that question.
Q. And if you look about halfway down, what FDA does here is they put a myth, and then they follow it up with a fact; correct?

A. Right.
Q. Go to the second page, please. The first bolded myth at the top says, "There are quality problems with generic drug manufacturing. A recent recall of generic digoxin called Digitek shows that generic drugs put patients at risk."
Do you see that?
A. Uh-huh.
Q. And then the FDA follows up with the fact.
"FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs, generic and brand name, are held."
Do you see that?
A. Yeah.
Q. Now, let's go down to Bullet Point 4.
A. Right.
Q. The second sentence says, "In our best judgement, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."
Do you see that?
A. Uh-huh.
Q. That's a yes?
A. Yes, I see it.

Q. Do you have any reason to disagree with FDA's statement about this situation?

A. I don't think so.

MR. MILLER: Objection. Scope.

Go ahead.

A. Yeah, I think so. Otherwise why would we be having this discussion here?

Q. Well, that's a really good question.

Did you do a more thorough investigation than the FDA?

MS. CARTER: Object to form.

A. I did an investigation based on the information provided to me for this product, yes. Did I do more than FDA? No.

Q. All right. Well, what's the basis for your disagreement with the FDA's statement on its own website regarding this very situation?

A. Well, I don't think the necessary investigation into the manufacturing -- in the manufacturing area was conducted. That is still my opinion.

Q. I understand that.

A. Oh, okay.

Q. But FDA doesn't say anything about the investigation of 70924; does it?

MR. MILLER: Object to form.
Q. In this document?
A. No, sir, it doesn't.
Q. Okay. It's commenting on the situation overall?
A. Uh-huh.
Q. And clearly, FDA knew about the investigation of 70924 because they put it in -- in a 483; right?
A. Right.
Q. So let me get back to this and make sure I understand. It says, "In our best judgement given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."
Do you have any reason to disagree with FDA in that statement?
MR. MILLER: Object to form. Asked and answered.
A. No. There is no reason to disagree with this.
Q. Okay. Is it your opinion that the investigation conducted by Actavis of the double-thick tablets in Batch 70924 was a cGMP failure?
MR. MILLER: I'll object to form.

MR. MORIARTY: Even when I ask you questions in your favor, you object.

Q. Go ahead.

A. I think that it was conducted in a way that it was aligned with cGMP. Was it conducted to what I would consider an adequate level? No.

Q. Was it negligent?

MR. MILLER: Object to form.

MS. CARTER: Object to form.

A. Was it negligent? Insofar as all the information wasn't there that I was looking for, I don't think it's negligence, but it certainly was not with the rigor that I would have expected.

Q. And that's your opinion?

A. That is my opinion, yes.

Q. Okay. Is there any specific FDA reg that says you need to -- you are required to analyze the batch before and the batch after in the course of an investigation like this?

MR. MILLER: Object to form.

A. I think it comes -- what it does, Matt, is it's customarily done. Is there a regulation that says you must do that? That's where business, science and regulations cross paths.

Q. All right. And the answer is?

A. I don't think -- I could sit here and look it up. I don't think you would ever find something that says that specifically.

Q. All right. In the course of your investigation in this litigation, did you look at the last Digitek batch which precedes -- batch record for the batch which preceded 70924?

A. I got a batch record that was close. That was the one I had mentioned earlier. That was the best I could do.

Q. And did you also look at one following close after 70924?

A. Not to date, no, sir.

Q. Have you asked for one?

A. Yes, sir. I haven't read it.

Q. Okay. Did you find any problems in the batch record for the batch that preceded 70924?

A. Preceded? Based on that one?

Q. Yeah.

A. Batch record? No, no, sir.

Q. So if Actavis would have looked at the batch record for the batch preceding 70924 in the course of the actual investigation, it wouldn't have found anything either; right?

MS. CARTER: Object to form.

A. My -- my guess, no. Because that's all part of rounding up the information. That's the first step.

Q. I'd like you to go to your report, please, which is --

MR. MORIARTY: Is it Exhibit 52?

MR. MILLER: Yes, it is.

Q. Your report is 14 pages long; right?

A. Yeah, yes, it is.

Q. Does the word "negligent" appear anywhere in these 14 pages?

A. Negligent? No, sir, I don't recall using that.

Q. Does the word "adulterated" appear anywhere in these 14 pages?

A. No, sir.

Q. Does the word "defective" appear anywhere in these 14 pages?

A. I don't recall.

Q. Okay. Let's go to Page 2. You comment under "Blending" that this is a dry blend direct compression process; correct?

A. That's right.

Q. Relatively speaking, is that a rather simple, solid oral dose formulation?

A. The answer is: It's simple, but it's risky. Okay? I hope that answers -- I'm not trying to be evasive.

Q. Go back, at the very end of the Introduction section. You are talking about your walk-through at Actavis --

A. Right.

Q. -- this year. It says, "During this inspection, all the equipment and related questions as related to the equipment were adequately addressed with no open issues."

A. Right.

Q. What do you mean by "no open issues"?

A. Everything I asked to see, I was able to see. Any questions I had were answered. Nothing was left open.

Q. Got you.

A. I was satisfied when I walked out.

Q. All right. Let's go to Page 4, please.

At the top, underneath the formula for Digitek --

A. Right.

Q. -- you are talking about "the amount of digoxin to be used in the batch is corrected."

A. Uh-huh.

Q. Etc., etc. Do you see that paragraph?
A. Yes.
Q. Are you talking about Batch 70924 specifically there?
A. Although 7029 -- 70924 is an example, I found that in the batch records I had, this is a common practice.
Q. All right. Well, that was a bad question.
Because what I really want to ask you about is the last sentence there. It says, "The blending process did not show any procedural issues or unexpected deviations from the established directions and planned deviations as set in place."
Do you see that?
A. Yeah.
Q. In that sentence, are you referring to 70924?
A. Yes, sir.
Q. In short, it appeared appropriately blended?
A. Absolutely, based on the information I reviewed.
Q. All right. Then in the next paragraph, you are talking about the blend sampling?
A. Yes, sir.
Q. And you talk about how they're withdrawn from the blender using a sampling feed.

A. Right.
Q. And you comment on that. And that's appropriate; right?
A. Yeah.
(A discussion is held off the record.)
Q. "Three sets of samples are taken to assure material is available should a repeat blend test be required."
Is that what you wrote?
A. That's exactly what I wrote.
Q. Is it appropriate to do that?
A. As we discussed this morning, yes, Matt, it is.
Q. All right.
A. And it's also in the guidance.
Q. Let's go to the next page. The question on tabletting.
A. Yes, sir.
Q. I'd say we can skip that. We covered that before.
A. Yeah.
Q. Let's go to Page 7, please.
A. Right.
Q. Under Investigation Report, the second paragraph.

A. Right.
Q. "The investigation report goes on to note that a potential root cause for the occurrence of the thick tablets may be an artifact of the compression machine start-up procedure."
Do you see that?
A. Yes, sir.
Q. And then you say, "This is credible."
What do you mean by that?
A. That it makes perfect sense to me.
Q. Does that happen in start-up in tabletting?
A. It happens with start-up all the time, Matt; yes, sir.
Q. Is that why you discard the first start-up tablets, because they can be out of spec?
A. That's why you pull away the equipment, you put reject buckets under it to discard it, right.
Q. Now, based on the number of times that my client's press operators went through the start-up process for this particular batch, did you make any attempt to estimate the number of tablets that would be produced during the start-up process?
A. No, I didn't.
Q. And you later comment in the next paragraph that a problem could occur if these oversized tablets

made during start-up got hung up in a deduster or metal detector; right?

A. That's correct.

Q. And have you seen that happen in your own --

A. Yes.

Q. -- work in the pharmaceutical --

A. Yes, I have.

Q. -- business?

A. And my walk-through assured me that the equipment used by Actavis, the likelihood that that happens is small; very visible, very, very easy to verify.

Q. All right. All right.

We're running out of time on the tape, so as much as I don't like to do it, we need to take a break.

A. Sounds good to me.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 2:54 p.m. This is the end of Tape Number 4.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 3:09 p.m. This is the beginning of

Tape Number 5.

Q. Dr. Somma, I was asking you some questions about your report.

A. Yes, sir.

Q. So let's go to Page 8.

A. Yes, sir.

Q. Now, so far as Batch 70924A is concerned, you are aware that my client, when it finished all of its inspections on that batch, found a total of 20 double-thick tablets. Is that right?

A. That's my understanding, yes, sir.

Q. Okay. Do you have an opinion to a reasonable degree of probability as to whether or not my client, in its inspection of that batch, failed to detect any other extra-thick tablets?

A. In my experience, we never relied on a visual inspection to release a batch.

Q. Sir.

A. I didn't answer the question.

Q. You didn't.

A. No.

MR. MORIARTY: Can you read that question back, please?

Q. It was a very specific question.

(The question is read.)

MR. MILLER: Objection. Asked and answered.

A. Okay. I don't -- the probability is they did not detect all of them.

Q. Do you have an opinion to a probability as to how many were made that were extra thick that were not detected?

A. I don't have a hard and fast rule, but my rule of thumb was if you see 20, you got a thousand. That's just Russ Somma's rule. Opinion, that's all.

Q. And Russ Somma's rule, is it based on controlled trials where you tried visual inspections and tried to see how many were caught or missed?

A. It's based on my experience in scale-up of processing. It has never been confirmed by taking them out and measuring if my rule is correct.

Q. Is it based on peer-reviewed literature?

A. No.

(A discussion is held off the record.)

Q. So it's not based on actual scientific studies where you compared visual inspections' accuracy to actual defect rates?

A. No, Matt, it's not.

Q. So I want to get back to my question.

Do you have an opinion to a probability as to how many extra-thick tablets were made but not caught

during the inspection of 70924?

MR. MILLER: Objection. Asked and answered.

A. It's hard for me to say, so I would have to say the probability is high that there would be more.

Q. But you can't give me to a probability a number?

A. A number, no, sir.

Q. So 70924 is then bottled; correct? Do you have an opinion to a probability as to whether there were extra-thick tablets in every bottle?

A. That would assume a uniform distribution across the batch. I can't say yes or no; however, I think the prudent approach was to dump them back and inspect again, which they did, yes.

Q. I understand that. I'm talking about after the inspection.

A. Oh.

Q. You are saying you think there were still extra-thick tablets that my client did not detect; right?

A. That's right.

Q. And you have no actual basis for that other than your experience --

A. My experience.

Q. -- that visual inspection is not that

accurate; correct?

A. That's correct, sir.

Q. Now, my client, after the inspection, 100 percent inspection and after the tight AQL, repackaged the batch; did it not?

A. Yes. They did.

Q. Into bottles; right?

A. Yeah, uh-huh.

Q. Do you have an opinion to a reasonable degree of probability as to whether there were defective tablets in all the bottles?

A. There were certainly defective tablets there that would not be detected. Would they be in all the bottles? I don't know.

Q. Do you have any opinion to a probability as to how many of those tablets that may have been defective actually made it into the prescription of a consumer?

(A discussion is held off the record.)

A. I didn't look at the field complaints, so I don't know. You know, that would be how I should have done it. I did not do that.

(A discussion is held off the record.)

Q. Well, the field complaints, unless the consumer got it and said, "this is a double-thick

tablet," the field complaint wouldn't necessarily tell you anything?

A. Exactly.

MR. MILLER: Object to form.

A. Exactly.

Q. So it is at least conceivable that if any extra-thick tablets got out, the number of which we don't know, it may have been a return to stericycle in the process of the recall. Correct?

A. I think that's a reasonable thought, yes.

Q. Do you have any basis at all to say that extra-thick tablets were made in the batch that was made before 70924?

A. No, sir.

MS. CARTER: Object to form.

Q. Do you have any basis in any of the material you have reviewed to say that there were extra-thick tablets made in the batch after 70924?

MS. CARTER: Object to form.

A. I think the only -- my only -- my only basis would be that they did not do a thorough enough investigation on the thick batch itself. That's the only thing. Did I see anything else? No.

Q. Would you concede that it is possible that the 100 percent inspection did get all of the

extra-thick tablets out of 70924 before it went to market?

MR. MILLER: Object to form.

A. In my opinion, it could not happen.

Q. It's impossible?

A. It's impossible.

Q. Have you got any basis for that?

A. Yeah, human fatigue. That's why we have vision systems for inspection. It's a fact.

Q. Well, how many -- how many people performed the 100 percent inspection?

A. Well, customarily you don't do 100 percent inspection unless it's part of your process.

Q. Dr. Somma, there is an actual document that talks about how many people did this inspection and how many days it took them to do it.

A. Right.

Q. How many people did the 100 percent inspection?

A. I don't recall. I'd have to guess.

Q. How many -- how many days did it take them to do it?

A. I don't recall.

Q. Go to the second paragraph on Page 8.

A. Right.

Q. Is it possible that the extra-thick tablets were within the API specifications?

A. It's very probable. Or very possible. Excuse me. It's possible, yes. We don't know what they were made out of, so possible.

Q. Third paragraph.

A. Right.

Q. The second sentence.

A. Right.

Q. Can you tell me what that means?

A. "Recorded observations when considered against the theory that such a tablet would have been randomly produced during the normal manufacture of tablets is without merit."

Meaning: In my opinion that this just wouldn't happen sporadically based on what I had seen. The -- you know, simply based on observations contained in the records.

Q. So if I understand what you are then saying --

A. Right.

Q. -- after that, it lends credibility to the theory that the start-up is the more likely time when double-thick tablets were produced?

A. I think, based on the evidence that I've

looked at, yes, sir. It gets back to that.

Q. Is that the most likely cause of what happened, in hindsight?

A. It certainly is one of the things I look to go to after I do an investigation -- a review of the batch records.

Q. Have you formed an opinion to a probability aboutwhat the root cause of the double-thick tablets in 70924 was?

A. My -- my opinion is the probability is about 50 percent that that is a result of start-up and shutdown of a piece of equipment.

Q. So it's 50-50?

A. 50-50.

Q. That's actually a possibility; correct?

A. A possibility.

Q. What are the other possibilities?

A. We go on to talk about a few of them, where the tablet itself would have adhered to the punch and rode around and back in and re compressed.

Q. Yeah, but you said that was unlikely --

A. Unlikely.

Q. -- in our experience.

A. Right.

Q. So that's not probable?

A. That's unlikely.
MR. MILLER: Object. Object to form.
Q. Isn't "unlikely" not probable?
MR. MILLER: Right, but you are asking for the remaining 50 percent, so...
Q. I haven't asked anything about the remaining 50 percent. This is one question at a time here.
MR. MILLER: Well, object to form.
A. My apologies for my selection of words. I find that possible, but not probable.
Q. Okay.
A. Okay? Does that help?
Q. Yes. That's the recompression?
A. Right. The --
Q. And you -- and you said up here that "randomly producing them during normal manufacture is without merit;" correct?
A. That is correct.
Q. And would not support random compression?
A. Right.
Q. So isn't that unlikely?
A. That is -- that's unlikely.
Q. All right. Do we have any other explanations that compete with start-up for the likely explanation?
A. Nothing that I would be able to come up with

other than -- yeah, other than complete speculation.

Q. And certainly in a -- what is this, a 45-station tablet press?

A. 45 station, double sided, yes.

Q. So it's 90 tablets at start-up per revolution?

A. That's right.

Q. Per press?

A. Right, there's two presses.

Q. So even if they only had one revolution per press at start-up, you are talking about 180 tablets; right?

MR. MILLER: Object to form.

A. Yeah, I -- I'd go with that.

Q. Okay.

A. Matt, I'd even say -- even if it is twice that amount. Because remember, this thing can move around. Let's just say it's -- say it's 180 exactly. All right?

Q. Let me just stick with the number of 180 tablets --

A. Okay.

Q. -- to keep my life simple here.

A. All right.

Q. Is it likely that my client's inspection

missed 160 extra-thick tablets in that batch?

A. It's possible.

Q. I asked if it was likely.

A. Likely?

Q. Yes.

A. I think it's likely.

Q. Okay. Is it likely they missed 360?

A. Wouldn't possible -- all 360? I can't -- as the number grows, I think it becomes more apparent; but --

Q. I'm asking a specific number. Isn't it unlikely that that many people inspecting over that amount of time with a product they're familiar with would miss that many?

MS. CARTER: Objection to form.

A. As the number grows, it becomes less likely; right.

Q. Well, the number grew from 180 to 360. It's already unlikely that they missed that many; isn't that right?

A. I would have to agree that they would miss all of them? No way.

Q. Let's go to Page 11 of your report.

A. Uh-huh, got it.

Q. On the second paragraph on that page, please.

A. Okay. This means?
Q. "This means that the drug or API used for the product must be well-characterized and understood."
Do you see that?
A. Yes, sir.
Q. "We did not see any data that indicated the firm did any physio --"
A. Physicochemical.
Q. "-- physicochemical review of the drug in problem batches."
First of all, what batches are you talking about?
A. In this particular case, and I apologize that it's not clearer, by "problem batches" I meant the two -- the batches that I looked at. One was that batch that had the blend issue, and the other was the -- the double thick tablet. That was the problem batches I've talk about.
And the comment to get to is simply that I didn't see the -- customarily in my experience, the culprit is usually the API, and you do a little more looking at the API.
Q. Which blend batch are you talking about?
A. Again, this gets back to the batch I looked at.

Q. Yeah, I want to know which one it is?
A. That's 71 -- 710 -- the other one I looked at, which is 71005.
Q. 71005? Do you have Batch Record 71005 with you?
A. Yeah, I do. It's right here. And the thing I'm looking at is there is an OOS investigation tag on the back; okay?
Q. Do you know whether 71005 was released?
A. I should be able to look here; right?
Q. To market.
A. I have a finished product release form. I guess it was.
Q. Okay. That's a 0.125 batch?
A. Yeah, yes, sir. Yes it is, yeah.
Q. And what do you mean by a physicochemical?
A. Customarily what we want to look at is that API itself is behaving as it was. These things have a tendency to drift in properties: Physical appearance, morphology, things like that.
It's something Actavis would have to do to monitor the guys selling the stuff to them. Okay? It's sort of a control of your supply chain.
Q. Do you know whether they test every batch of active pharmaceutical ingredient that they receive?

A. I looked at the ANDA for Digitek, and it was clear to me that they tested all the incoming batches based on the ANDA. All incoming batches of API.

Q. Okay.

A. Right.

Q. So is that the kind of physicochemical review you are talking about?

A. No, Matt. It usually goes a little bit beyond that, and they did do that. I've seen evidence of particle size determination by a Malvern synthesizer when I did my walk through. But there's other things you look at: Thermochemistry, morphology, searching things under a microscope.

(A discussion is held off the record.)

A. This is stuff that I customarily look at when I'm doing such an investigation.

Q. Okay. I want to get back to something I was asking you before, because I forgot something. And I'm sorry if I'm repeating anything I went over this morning.

I asked you whether you had any basis to say that there were thick tablets made or released in the batches before and after 70924. Do you remember that question?

A. Yes, sir.

Q. All right. Do you have any basis to say that there were extra-thick tablets made and released to market in any other Digitek batch in 2005 or after?

A. Without having the root cause in front of us, I would say is it one-off? I can't say yes or no. So the answer is: Based on the information you presented as far as testing goes, that certainly supports there were.

My opinion is, until you have done the investigation to the level I'd expected, it's possible.

Q. Do you have any opinion to a probability what the kind of investigation you think should have been done would have revealed?

A. Yeah. Number 1, it would have identified compressability. It would have identified flowability. It would have identified any changes in morphology. And these things are all in the literature and they are in your citations -- the citations I gave you. And not only that, it's also stuff that I customarily do.

What I would be looking for is any change in crystal structure. Even at the low dose we have, it can make these things more sticky or less sticky; it can cause more flow or less flow; and things that can

happen in the background without your knowledge. Okay?

Q. But as far as I understand it, and you have certain batch records that you looked at and you have other batch records available on the plaintiffs' lawyers' website of documents; correct?

A. Uh-huh.

Q. Yes?

A. That's correct.

Q. Mark doesn't understand um-um and uh-huh.

A. Yes, yes.

Q. Okay? But you didn't see -- you don't talk about in your report problems with extra-thick tablets in any other batches before or after 70924; right?

A. That's correct.

Q. So it's conceivable that a good, solid investigation would have revealed that they just left some start-up tablets in the deduster and that it was not a common problem to other batches; right?

MR. MILLER: Object to form.

A. If I -- I would -- I would agree, had I not looked at the quality of the deduster that Actavis uses. It is not likely that that is the case.

I agree there that's a credible excuse, Matt; but after my inspection, it's not likely.

Q. Well, a good solid investigation could have found a root cause that was just a one-off; right?
A. Usually -- My point exactly. A one-off, if you agree that it's a one-off and everybody says it's okay and you move on, is fine, as long as you are absolutely certain it's a one-off.
Q. It's pretty hard to always be absolutely certain; isn't it?
A. Yes. Uh-huh.
Q. You said yes; right?
A. Yes.
Q. Have there been many times in your work in the pharmaceutical industry where you didn't come to a root cause?
A. Yes.
Q. Okay. Page 11.
A. Uh-huh.
Q. Fifth paragraph.
A. "The attributes"?
Q. Yes.
A. Uh-huh.
Q. The second sentence I don't understand.
A. Okay.
Q. "Tablet weight assures the proper level of API is contained within each tablet."

Do you see that?
A. Yes, sir.
Q. Is that true?
A. "The tablet weight assures the proper level of API is contained in each tablet."
That is true because the blend feed stock is uniform.
Q. Okay.
A. Right?
Q. I mean you could have a proper weight tablet that's 100 percent excipients; right?
A. Exactly the point, Matt. And that -- but that speaks to the blend, not the tablet.
Q. All right. And presumably that's why you do finished product testing?
A. Yes, but remember: One of the things we as an industry suffer from is end-use testing. End-use testing is not adequate in most cases to control the process.
Q. Did you ever see any place where FDA cited or warned Actavis, or even Amide, for the use of Stokes' BB2 tablet presses.
A. I don't recall seeing stuff about that.
Q. The fact that --
A. There was a question about their

qualification, but not the use as I recall it.

Q. Have you ever seen anything in the material that says that the Stokes machines weren't qualified?

A. I'd have to actually -- to be -- I vaguely remember seeing something about qualification. Whether it was the Stokes or not, Matt, I have to say I don't know. I'd have to go and look.

MR. MILLER: Well, you can take your time and look if you need to.

Q. Can you answer while you look?

MR. MILLER: No.

Q. Can you multi task?

MR. MILLER: No.

Q. Let me ask you a couple of questions before you look.

A. Yeah.

Q. FDA was well aware that my client was using Stokes BB2 tablet presses from the ANDA and every batch record; correct?

A. Absolutely. Batch presses are noted in the ANDA, yes.

Q. Even after Batch 70924, did FDA ever give a 483 or warning letter about the use of Stokes BB2 tablet presses?

A. No, I don't recall that.

And, again, my only question was whether or not they did their homework on qualifying. Okay? That's it.

Q. Is there any CFR or any other regulations requiring the use of tabletting equipment with weight controls?

A. Again, CFRs are meant to give equipment -- excuse me -- to given industry guidance, but not to mandate how they run their business. So there is no mandatory requirement that they run an instrumented tablet press.

Q. Okay. Have you ever seen any evidence that Digitek was cross contaminated with any other product?

A. Absolutely not.

Q. When there is equipment, tabletting equipment with weight controls, do they typically weigh all the tablets, or is it random sampling?

A. Well, Matt, tablets -- with a weight control system does not weigh tablets. What it weighs is the force applied to form the tablets. So what it does is it monitors the pressure in a finite environment.

To clarify, it measures every one, every tablet is measured. It's not necessarily weighed. It's indirect. Okay?

Q. Let's go to Page 13 of your report.

A. Yes, sir.
Q. It says, "The data for digoxin manufacture that we reviewed show a lack of appreciation of the dangers of this compound."
My client has made billions of digoxin tablets. How many have you been involved in making?
A. I never made digoxin, sir.
Q. So what is the basis for your statement that my client shows a lack of appreciation for the dangers of the compoundinig?
A. It seems to me that my involvement with highly potent products in the past, which is more in -- highly potent means low dose, as taken here; that more care is given to maintaining their weight, assuring homogeneity. That's all. That's what I'm trying to say.
I was comparing it to people making highly potent compounds.
Q. Well, so far as weight is concerned, did you find evidence in the material that you reviewed that there were batches which made it to market that had weight issues?
A. Not based on the run -- the run sheets I looked at, no.
Q. Okay.

A. But, again, understand that the weight of the tablet is not an indicator of its uniformity.

Q. I know. But you just used weight as an example?

A. True, but weight is in fact only an indicator of the dosage form. We get right back to the fact that the dosage form itself has to be uniform, and what I'm trying to be clear about is: You could have a uniformly weight -- a uniform weight batch, tablets right down the middle, but the blend that goes to feed that material has to be uniform, so that each aliquot is the same.

I'm sorry, if I misunderstood -- if I misunderstood.

Q. And you are basing that on the less than a handful of blend investigations that you saw in these materials. Is that right?

MR. MILLER: Object to form.

A. Here again, in my profession, usually we are brought in, we are not given all of the details. The answer (sic) is: Do we see a potential problem? And based on the information I was presented, the answer is: Yeah.

I looked for the usual candidates that lead to problems, and they were all there. Lack of

investigation, lack of understanding of the API, you know, in general.

There's a lot of investigations, Matt, and there's not a lot on the side -- you know, not a lot that focus on the things that I would have looked at.

Q. What do you mean in the next paragraph by "The firm lacks the fundamental understanding of the need to define the requirements of the product to be manufactured and take actions within their supply chain"?

A. That gets back to my API point. If, in fact, they didn't look at the API, how would they be able to feed back into their supply chain that they are getting the necessary material for the necessary functionality purpose. That's all I'm saying.

Q. Have you ever seen any FDA 483 or warning letter indicating that Actavis did not pay adequate attention to its API -- raw API?

A. I don't think that they were cited specifically on that, no.

Q. Do you have any information at all that shows that active pharmaceutical ingredient that was of inappropriate potency or purity was used in Digitek?

A. No.

Q. Does -- At Page 14 --

A. Yes.
Q. -- you are talking about V-shaped blenders and double-cone blenders --
A. Right.
Q. -- being of different geometry; right?
A. Right, uh-huh.
Q. That's a yes?
A. Yes, sir.
Q. Does FDA actually consider them part of the same family?
A. Yes, they do.
Q. What do the SUPAC guidelines say about the use of V-shaped and double-cone blenders in the same --
A. They're in the same class, but different sub classes.
Q. Does SUPAC specifically say not to use them in the same drug production?
A. It doesn't given you that guidance. When we put SUPAC together, we dealt with that question specifically to give industry flexibility, but it requires that the owner of the firm assure that that's done properly.
Q. So the bottom line is: My client's use of this blender configuration doesn't violate any --

A. Any regulation.
Q. -- regulation or guidance from SUPAC; right?
A. No, sir.
Q. Now, I've asked you a lot of questions today about whether you had evidence of out-of-spec Digitek making it to the hands of consumers. I don't need to rehash that.
But as we've gone through that, when I've been asking about out-of-spec tablets getting to consumers, what have you understood that to mean?
A. My understanding was out-of-spec tablets getting to consumers -- I've taken that simply from the analytical perspective. Okay? In other words, you have a set of specs and you test it. Right?
Q. Okay. Do the analytical specs include weight and thickness?
A. I believe those are in the testing monograph.
Q. And the testing monograph includes the range for the active pharmaceutical ingredient; right?
A. That's correct.
Q. All right. Anywhere in your report, did you say that tablets, either extra thick or outside the USP's active pharmaceutical ingredient specifications made it to the hands of consumers?
A. No, sir, I didn't make that statement.

MR. MORIARTY: Adam, how much time left do we have on the tape?

THE VIDEOGRAPHER: We have I'd say a full 40 minutes left.

MR. MORIARTY: Okay. Let's just take a --

Do you have questions that you know of right now?

MS. CARTER: One or two.

MR. MORIARTY: Let's take a five or ten-minute break. Let me go through all my notes with Ms. Downie and we will see where we are and be in a position to wrap this up. Okay?

MR. MILLER: Okay.

THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 3:48 p.m.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 4:04 p.m.

Q. Dr. Somma, I have a couple exhibits that I hadn't asked you about yet. I'm anxious to lighten my load.

This is Exhibit 9. It's MOI145.

You know what an MOI is; don't you?

A. Yes, sir.
Q. Method operating instruction?
A. Yes, sir.
Q. Have you seen this document?
A. I have seen it, yes, sir.
Q. I didn't notice any criticisms --
A. No.
Q. -- in your report about MOI145?
A. No, sir.
Q. You don't have any criticisms of it?
A. No, sir.
Q. This is Exhibit -- it's actually Plaintiffs' Exhibit 159. Have you seen this document before?
A. Yes, sir.
Q. This is a blend failure investigation?
A. Uh-huh.
Q. Is that a yes?
A. Yes, sir.
Q. Is this one of the documents you were relying on for your opinions about the blend issues in this situation?
A. Yes, sir.
Q. And lastly, this is Exhibit 288. And I'm sorry, I can't tell you whether that's Defense or Plaintiff's Exhibit 288, but it's 288.

MR. MILLER: It's plaintiffs'.

MR. MORIARTY: Is it? Oh, it says, "Plaintiffs" on it. That's a pretty good hint.

(A discussion is held off the record.)

Q. Have you seen this document before?

A. I've seen test reports of blend assay, not this specific one.

Q. Okay. Is this an investigation of a -- either a planned or an unplanned deviation in blend uniformity? And I see in here some planned deviations, and then in the back I see an out-of-spec investigation.

Do you know what this document is?

A. I haven't looked through it yet.

Q. Did you rely on it in forming opinions in this case?

A. No, sir.

Q. All right.

A. Not that I recall.

Q. Okay. Then I won't ask you about it.

A. Okay.

Q. Does FDA have a good scientific reason to take 484 samples and test them?

MR. MILLER: Object to form.

A. That's a good question -- that's a good

question. I don't think I know the answer. From a scientific standpoint it's to confirm that you've done what they told you to do. Isn't that called -- isn't that part of vigilance, follow-up, I guess?

Q. If either Actavis' finished product testing or any testing done by Celsis Labs or any 484 sampling and testing done by FDA had been out of specification regarding Digitek, do you think that would have been important to your opinions?

A. Yes.

Q. On the flip side of that coin, isn't the absence of out-of-spec testing by all three of those entities unfinished product testing significant?

MR. MILLER: Object to form.

MS. CARTER: Object to form.

(A discussion is held off the record.)

A. I think it's significant.

Q. Did you perceive your role in this consultation to be to assess whether there were potential problems with the production of Digitek?

A. If there was a -- a problem that was not identified, perhaps; something that was not seen before.

Q. In other words, a potential problem?

A. A potential problem.

Q. And "potential" is really "possibility"; is it not?

MR. MILLER: Object to form.

A. I guess I'd have to put it in that category of possible, yeah.

Q. And the existence of a potential problem does not always mean that there is an actual problem. Is that right?

A. Unless you go about answering the question in the investigation; then you can't say if it's potential or not. But that's how I do business, how I do my job.

Q. And just to make sure I understand your thoughts on this case completely, are you saying that Actavis was, in fact, producing Digitek outside the specifications, and it's just a sheer coincidence that none of it was detected by Actavis, FDA or Celsis or pharmacists?

MR. MILLER: Object to form.

A. I would say yes.

Q. What's the scientific basis for you to say that?

A. Because without identifying as these issues myself, the potential with the blend, the observations I made with the blend, that they -- in here; the

observations with even the heavyweight tablets or whatever we call them, double-thick tablets, I am not thoroughly convinced that the investigation into the root cause uncovered all the potential issues. To my satisfaction.

Q. Are you done with your answer?

A. Yes, sir.

MR. MORIARTY: Can you read that back, please, from the "I'm not thoroughly convinced" part.

(The answer is read.)

Q. Would you agree with me that the fact that Russ Somma is not thoroughly convinced that the investigation uncovered all of the problems to your satisfaction does not mean that consumers actually received out-of-specification Digitek?

MR. MILLER: Object to form.

A. That I am not convinced, me? I am not convinced that they --

Let me have the question again, please.

I'm sorry, Matt.

(The question is read.).

A. Gee, I must be thick. I'm sorry.

Q. Okay. That's fine. If you don't understand it -- or it's late, it's late.

A. I'm a little thick. I'm sorry.

Q. You told me --
A. Yeah.
Q. -- just a minute ago that you weren't thoroughly convinced that the investigation of 70924 uncovered all the problems to your satisfaction?
A. Right.
Q. Correct?
A. That's correct.
Q. That's your opinion --
A. That's my opinion.
Q. Russell Somma?
A. Right.
Q. Correct?
A. That's right.
Q. Just because you are not thoroughly convinced that that investigation uncovered all the problems to your satisfaction does not necessarily mean that consumers actually got Digitek that was outside the specifications. Isn't that correct?
MR. MILLER: Object to form.
A. Everything I've looked at Matt, you know, for me to agree with you, I would have to be convinced that this information is there, and I'm not. I'm really not. If this was Novartis and you asked me that and you were -- you were my superior, my

recommendation is no, I'm not convinced and, therefore, I'm not comfortable with the situation. That's just the way I am.

Q. Well, are you asking me to prove to you that there weren't defective tablets in the hands of consumers?

MR. MILLER: Object to form.

A. No, I'm -- I want to see information that was done in a rigorous enough fashion that I am convinced. Sorry.

Q. All right. That's not my question.

A. I'm sorry.

Q. Okay. The purpose of this lawsuit is not for you to be convinced about the rigors of this investigation.

A. Okay.

Q. All right? I thought I'd asked this many times before today, and I don't want to rehash it and go on and on and on.

I haven't heard you say anything today where you say to a probability that you have some scientific proof that consumers got out-of-specification Digitek.

MR. MILLER: Object to form. If there's a question.

Q. Are you changing your opinion in that regard?

A. No, sir.
Q. Okay. So do you see what I'm trying to drive at here? Your level of -- your not being thoroughly convinced that the investigation revealed problems with that one batch does not prove that there was out-of-spec Digitek in the hands of consumers; does it?
MR. MILLER: Object to form.
A. And, again, what I have to point to is that all of the parts have to move and have to work properly. And there's certainly information that says in general, the quality systems here were not functioning properly.
Q. Give me all the affirmative, scientific evidence that you have that any consumers got out-of-specification Digitek in their prescription vials?
A. And, again, if all we rely upon is the specifications, we wouldn't be having this conversation. The answer is: There's got to be another dimension to it, and that dimension is the way in which they manufactured the product, and that is the point I keep trying to make.
I haven't seen anything beyond: They meet specs. If you live by the specs, you die by the

specs. It's as simple as that. That's a narrow-minded approach. And I agree with you, they all met spec.

MR. MORIARTY: I'm going to pass the witness to Ms. Downie.

CROSS EXAMINATION BY MS. DOWNIE:

Q. Dr. Somma, I have just a few questions for you.

You testified earlier today that you were contacted initially by Spyglass, Mr. Kenny's organization. Is that correct?

A. That's correct.

Q. And when were you first contacted by Mr. Kenney?

A. In March.

Q. How many times have you spoken with him regarding this litigation?

A. Two -- three times.

Q. And when he first contacted you, what did he tell you he expected your role to be in this litigation?

A. To be the technical opinion.

Q. And did he provide to you details regarding what the litigation was about?

A. Other than the fact that an oversized tablet was distributed, no. That's all I understood.

Q. Do you recall any other specifics of that conversation?

A. The conversation revolved around: Had I seen problems like this before, what is my opinion. That's about it.

Q. And had you seen problems like this before?

A. Yes, the same that I outlined before.

Q. Okay. And you said you had spoken to him about two or three times?

A. Right.

Q. Do you recall the substance of your conversations subsequently?

A. The next one was we met on Crivella to talk about the information, and then we decided -- you know, we wanted to make sure that what I focused on as far as content was something -- was nothing that he had -- that he had focused on, I guess what I'm trying to say; to understand what our approach was going to be.

Q. Why was it important that your opinions not overlap?

A. I wanted to make -- I wasn't going to produce something that was -- in other words, as I understood

it, I told you what my limitations are. I'm not a regulatory person. I'm not a compliance person. So my point was: I looked at the technical dimension. That was it.

Q. And what do you understand his role to be?

A. My understanding is, Mark is quality assurance.

Q. Quality assurance?

A. That's my understanding.

Q. Have you taken a look at his report?

A. No, sir.

No, ma'am. Sorry.

Q. That's okay. It's been a long day. I won't take offense.

Have you discussed with him what his opinions are?

A. No, ma'am.

Q. You just discussed what the scope of his opinions would be?

A. I discussed what -- where he would come down as to what his definitions and his assessment would be; not the scope.

Q. What did he tell you his definitions of --

A. Quality assurance, quality systems; you know, these kind of things that lead up to that.

Customarily when we do a technical investigation, we don't go down and drill through training manuals and SOPs. Okay?

Q. How long -- Or how many times have you worked with Mr. Kenney in investigations --

A. Never before.

Q. -- before consulting --

A. Never before.

Oh, I'm sorry. Never before.

Q. And are you -- have you been retained by Spyglass or are you retained by the plaintiffs' counsel in litigation?

A. I work for -- I work for Motley, Rice, plaintiffs' counsel.

Q. Okay. Were you given any kind of consulting fee or did you pay any consulting fee to Spyglass?

A. No, I did not.

Q. Okay.

A. This was something, when -- when we first talked, this was -- this was sorted out between myself, Motley, Rice and Spyglass. And Motley, Rice gave us the direction and we were totally separate.

Q. Other than Mr. Kenney, have you spoken to any other individuals regarding this litigation, other than of course plaintiffs' attorneys?

A. Sal Romano, who works with Mark Kenny.
Q. And how many times have you spoken -- I'm going to say Sal, because I'm not sure of the last name.
A. Right, Romano.
Two times, as far as I recall.
Q. Two times. And what were your discussions with Mr. Romano?
A. The initial investigation -- the initial interview, if I had the background in tabletting. Okay? And the second time was when we trained on how to use Crivella.
Q. Remind me again what Crivella is?
A. Crivella is a database --
Q. Right.
A. -- that all of this stuff is on. C-r-i-v-e-l-l-a.
Q. That's right. That's what you looked at the batch records on; is that correct?
A. That's where the batch records are.
Q. Why are the batch records important for you to review?
A. Batch records to me are the manner in which the company manages that part of the manufacturing. This is the hands-on approach that the operator does,

it's his direction, and that's his personal interface. That's the human interface, in my opinion. It also is a reflection of all of the sum total knowledge from development to maturation, it's in the batch records. This is how you make it.

Q. And I believe it was your testimony earlier that you believe that Actavis should have reviewed the batch records before and after?

A. That's an opinion, yes.

Q. That's right. And you have only reviewed the batch record that occurred prior. Is that correct?

(A discussion is held off the record.)

A. As close as I can get.

MR. MILLER: Asked and answered.

(A discussion is held off the record.)

Q. How many times have you personally been involved in a visual inspection of the type that was conducted by Actavis?

A. Two times.

Q. When were those?

A. I would have been -- guessing now, early '80s, and these were primarily in a clinical dosage form area. But again --

Q. What were the context of those individual

inspections, why were they being conducted?

A. In those particular cases, we were looking for capsules, if I recall. I think it was a cracked capsule.

Q. You were looking for cracked --

A. Cracked capsules.

Q. In both instances?

A. In one instance, I think. I think the other one what is I recall was a double debossed problem. It's kind of like a -- it's not a double thick, excuse me. It's sort of like an overwritten imprint. That was a total bust, by the way.

Most of my other have been systems, electronic systems.

Q. Okay.

MS. DOWNIE: I don't have any other questions. Thank you.

MR. MORIARTY: I think I just have one more.

REDIRECT EXAMINATION BY MR. MORIARTY:

Q. In that private consulting engagement you had with the extra thick tablets, was anyone asked to prove whether thick tablets were -- actually got to consumers?

A. I believe it was reacting -- I think it was

as a result of a field complaint. And, again, I didn't get deeply into that, but my understanding was a field complaint. Because there was subsequent regulatory action as I recall as a result.

Q. Is that what started the investigation?

A. I believe so.

Q. Okay. So the fact that there was a field complaint, do you know whether it was from a pharmacist or a consumer?

A. That I don't recall, Matt. I don't.

Q. All right. Well, a field complaint, was it pharmacist or consumer?

A. To be honest, Matt, I don't know. You know, because I realize that they can come in by various conduits. To be perfectly honest, I don't -- all I know is: We got a complaint.

In my business, if I got a complaint from the field. To me that means, well, somebody caught it outside the confines that you have control ove. That's bad. Okay? That's how I took it. How it came in, Matt, I can't tell you. I don't know.

Q. It's bad, but it happens?

A. It happens.

MR. MORIARTY: All right. I don't have any other questions.

MR. MILLER: I have a couple of questions.

RECROSS EXAMINATION BY MR. MILLER:

MR. MORIARTY: And, again, I object in general to you asking your own experts questions in my deposition. But go ahead.

MR. MILLER: Okay.

Q. Dr. Somma, do you have an opinion to a reasonable degree of probability that Actavis released the product Digitek outside of specification with regard to thickness specifications over the course of time that the recalled products were manufactured?

A. Yes.

Q. Do you have an opinion to a reasonable degree of probability that out-of-specification Digitek tablets were released during the time of manufacturing for the recall product that were out of specification for blend uniformity specifications?

A. Welt, that's certainly a tough one, but the answer is, again, based on what I looked at because, you know, the blend question itself in my opinion has not been resolved to an adequate level, I would have tosay yes.

Q. We went over the opinions in your expert report. Other than the information that you had

corrected --

A. Right.

Q. -- that you had picked up yesterday, has anything been shown to you or said today that alters any of the opinions that you have in your report?

A. No. We talked about the sample frequency. I was wrong there. Okay?

Q. Right. We covered that.

A. Okay. Other than the fact that I obviously made that one mistake, these are still -- these bullets are still -- are what I've put down and these are my opinions based on what I've read.

Q. Do you hold these opinions to a reasonable degree of probability?

A. Within the same probability that we have been discussing today, yeah.

MR. MILLER: I have no further questions.

MR. MORIARTY: Okay. I have more now.

RE-REDIRECT EXAMINATION BY MR. MORIARTY:

Q. Let me see if I can make sure I understand.

Mr. Miller asked you if you had an opinion to a reasonable probability about whether my client was releasing Digitek that was too thick over the course of the time of the recalled batches.

Do you remember that question he just asked you?

A. Uh-huh.

Q. How many batches?

A. How many batches were recalled?

Q. No. How many batches had extra-thick tablets that were released?

A. I'm -- that I -- the probability of giving you that number, I don't know.

Q. Which batch numbers? Which batch numbers had extra-thick tablets?

A. I think -- I'm thinking about this that this had happened and gone undetected. In that case, how would I know the batch numbers?

Q. Well, how would you know it happened and went undetected? What's that based on?

A. Simply -- simply the lack of rigor that was conducted and the way they analyzed the problem.

Q. On 70924?

MR. MILLER: Object to form.

Q. That's the batch you said had no rigor; right?

A. Yes

MR. MILLER: Object to form.

Q. Okay. That was December of 2007; correct?

A. Uh-huh, uh-huh, yes, it is.
Q. So tell me what basis you have whatsoever to say that out-of-spec tablets that were too thick ever left Actavis's premises before that even happened in 2007?
A. Well, there was the one report on the 2000 -- in 2004; right? For a thick tablet.
Q. Yeah.
A. Okay. Right?
Q. Okay. Anything else?
A. No.
Q. So out of the billions that were made, we have one tablet that actually made it to a pharmacist out of billions; correct?
A. Uh-huh.
Q. Yes?
A. That's correct, sir.
Q. And that's your basis for an opinion to a scientific probability that this was an ongoing problem?
MR. MILLER: Object to form. It misstates previous testimony.
A. Again --
Q. Yes or no?
MR. MILLER: No.

Q. Is that your basis to say that this was an ongoing problem?
A. Yes.
Q. All right. So I want to get back.
What batches and how many batches, give me the numbers, give me how many?
MR. MILLER: Objection. Asked and answered.
Q. Is the answer: You can't do it?
MR. MILLER: Objection.
MR. MORIARTY: Well, if it was answered, that was the answer I heard.
MR. MILLER: Well, you heard wrong. That's not what he said.
MR. MORIARTY: Okay.
MR. MILLER: He said he didn't know.
Q. Got any field complaints you can show me?
A. No, sir.
Q. Got any test results you can show me for thickness or weight?
A. Nothing other than what you showed me.
Q. Do you have anything scientific that you can show me besides the 2004 incident, between then and the end of November 2007, anything at all?
MR. MILLER: Objection. Asked and answered.
A. Again, everything I've looked at -- All

right? -- from a scientific basis indicates that there is a product that was released, it was within the requirements. Does that mean all of the -- there is nothing else going on?

And, again, this is simply my opinion. And in my opinion, without more investigation or better rigor than that, I can't tell you if it got out there. Is the evidence there? There is one tablet in '04 and that was it.

Q. So it is your opinion, but when I ask you for a scientific proof of the opinion, you can't point to a document in the materials you've looked at. Is that right?

MR. MILLER: Object to form.

A. There was nothing in here that clearly drew that conclusion, correct.

Q. Okay. Then the next opinion you had that Mr. Miller asked you about was essentially the same question: Did you have a reason -- an opinion to a reasonable probability that there was something about out-of-spec blend uniformity that made it to end release.

Do you remember that question?

A. Yes.

Q. Okay. Let's get -- let's get accurate about

what happens. If, in fact, there is a blend uniformity that is truly out of spec, it leads to the possibility that there will be more active pharmaceutical ingredient in some part of the batch and less in the other; correct?

A. That's correct.

Q. And a batch is not released that way; it is tabletted --

A. That's right.

Q. -- and then it goes out; correct?

So the theory would be that some tablets in that particular batch might have too much and others might have too little of the active pharmaceutical ingredient; correct?

A. That's correct.

Q. All right. Now, I don't want to plow old ground over and over, because I've asked you this before. But can you identify any field complaints where that was documented to have occurred?

MR. MILLER: Objection, asked and answered.

Q. In the material you reviewed.

A. Right. No.

Q. Can you document any test results to indicate that that actually occurred?

A. Not that I recall.

Q. Can you identify any batch by number where that occurred?

MR. MILLER: Objection. Asked and answered.

A. I think the answer was no for that.

Q. Can you identify how many batches in which that occurred?

MR. MILLER: Objection, asked and answered.

A. Again, that -- that gets into that point that I really can't make an estimate.

Q. All right. And the last question is: If that ever occurred, you can't quantify how many tablets were high or low; right?

A. Exactly. As we discussed.

MR. MILLER: Objection. Asked and answered.

A. And I apologize.

MR. MILLER: We are done.

THE VIDEOGRAPHER: Please stand by.

MR. MORIARTY: Well, stay on mark's record. You can go off the video.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 4:36 p.m. This is the end of Tape Number 5.

MR. MORIARTY: Exhibit 51A is the little white box of thumb drives. Do you have any problem with me taking this in my briefcase back to my office?

MR. MILLER: Those are three thumb drives that were produced for you.

MR. MORIARTY: Yes.

MR. MILLER: So those are yours.

MR. MORIARTY: Okay. So I don't have to leave them with the court reporter.

MR. MILLER: Right. We'd just like to have a note in the record, which is already there. So, yeah, fine.

MR. MORIARTY: I'll take them.

(The witness is excused.)

(The deposition is adjourned at 4:37 p.m.)

* * *

C E R T I F I C A T E

I, MARK SCHAFFER, a Shorthand Reporter and Notary Public of the States of New York and New Jersey, do hereby certify that prior to the commencement of the examination the witness was sworn by me to testify to the truth, the whole truth and nothing but the truth.

I do further certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I do further certify that I am neither of counsel nor attorney for any party in this action and that I am not interested in the event nor outcome of this litigation.

MARK SCHAFFER, C.S.R.

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Commission No. 55985 Expiring September 13, 2011
Notary Public of the State of New York
Registration No. 01SC4953912 Expiring July 31, 2011

BOBBY R. MILLIGAN, et al.,)
)
Plaintiffs,)
)
vs.)
)
ACtAVIS GROUP HF, et al.,)
)
Defendants.)
----------X

I have read the foregoing transcript and found it to be a truthful and accurate representation of the testimony I gave in connection with the captioned matter on_____.

_____
RUSSELL SOMMA, PhD

The State of:
County of:

Sworn and subscribed before me
this day of , 2010
My commission expires:

E R R A T A S H E E T

Please list any correction with the corresponding page and line numbers.

PAGE	LINE	CORRECTIONS
1.		:
2.		:
3.		:
4.		:
5.		:
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8.		:
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